A DISSERTATION ON

STUDY ON COMPARISON OF CERVICAL LENGTH MEASURED TRANSVAGINALLY AND BISHOP SCORE IN PREDICTING SUCCESSFUL LABOUR INDUCTION

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MADRAS MEDICAL COLLEGE CHENNAI

APRIL 2016

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ABBREVIATIONS

FFN	-	Fetal Fibronectin
MMP	-	Matrix Metalloproteinase
TVU	-	Trans Vaginal Ultrasound
TVU CL	-	Trans Vaginal Ultrasonic Cervical Length
PTB	-	Preterm Birth
PPROM	-	Pre term Premature Rupture Of Membrane
LIF	-	Light Induced Fluorescence
FHR	-	Fetal Heart Rate
PGF2α	-	Prostaglandin F2α
PGE2	-	Prostaglandin E2
IOL	-	Induction of Labor
MU	-	Montevideo Unit
kPas	-	kilo Pascal second

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Introduction

INTRODUCTION

Induction of labour is a process where uterine contractions are initiated by medical or surgical means before the spontaneous onset of labour and is carried out in approximately 20% of pregnancies.[1] The commonest indication for induction is prolonged pregnancy, and several studies have shown that induction, compared to expectant management, is associated with a substantial reduction in perinatal mortality.[2-4] Predicting whether an induced labour will result in successful vaginal delivery is based on the pre-induction favorability of the cervix as assessed by the Bishop score is the traditional method. However, this assessment is subjective and several studies have demonstrated a poor predictive value for the outcome of induction especially in women with a low Bishop socre.[55]

Transvaginal ultrasonography has gained increasing application in obstetric in the area of induction of labor. Transvaginal cervical length measurement has primarily focused on detecting cervical changes in women at risk for preterm delivery.[6] Theoretically, transvaginal ultransonographic measurement of the cervix could represent a more accurate assessment of the cervix than digital examination, because the supra vaginal portion of the cervix usually comprising about 50% of the cervical length is very difficulty to asses digitally in a closed cervix. In addition, the assessment of the effacement which starts at the internal OS will be difficult to predict in a closed cervix. In contrast transvaginal sonographic measurement of the cervical length is

quantitative and easily reproducible method of assessing the cervix which can be achieved easily with minimal discomfort to the patient.

This study was done to determine if transvaginal ultrasound, with it's ability to objectively measure the cervical length, could predict the outcome of induction better than clinical assessment obtain by the Bishop score.If so, transvaginal ultrasonographic measurement of cervical length can be used as an adjunct tool to the traditional Bishop score and add yet another dimension of information in the field of successful induction of labour.

Aims and Objectives

AIM & OBJECTIVES OF THE STUDY

1. To compare the predictive value of the Bishop score and transvaginal ultrasonography in successful labour induction.

2. To estimate the most useful cutoff points for the two methods.

NEED FOR THE STUDY:

Induction of labour is one of the common interventions in obstetric practice. Cervical assessment has been used as a prediction of the successful vaginal delivery. Traditionally, the bishop score has been used to assess the cervix. Bishop originally observed that nulliparous women undergoing induction of labour with a cervical score >8 had the same likelihood of vaginal delivery as did women in spontaneous labour.[7] Labour induction with a low cervical score has been associated with failure of induction, prolonged labour, and a high rate of cesarean deliveries.

Transvaginal ultrasonographic measurement of cervical length has been linked, during recent days, with the risk of preterm delivery.[8] Cervical shortening, as seen in sonograms, has been proposed a proof of the process of cervical effacement.[9]

A text book of obstetric described a successful labour induction as the initiation of labour.[10] Active labour, represented by cervical dilatation of 3-4cem or greater in the presence of uterine contractions, is usually considered a reasonable threshold for diagnosis of labour because of the uncertainties in diagnosing true labour during earlier stages of cervical dilation.

This study is designed to investigate transvaginal ultrasonographic cervical measurement as a predictor of duration of labor and successful induction resulting in vaginal delivery and also compare the performance of ultransonographic cervical measurement with that of the Bishop score in predicting the outcome of labour induction.

Review of Literature

REVIEW OF LITERATURE

Pre induction scoring to predict successful labour induction- Historic Perspectives:

More than 12 different pelvic or cervical scoring schemes have been described during the past 70 years, but the semi quantitative clinical scoring system described by the bishop is the most widely employed (Bishop 1964)

Fetal Fibronectin (FFN) concentrations in the cervical transudate represent a laboratory approach and have been shown to correlate with induced labour outcome with concentration <50mcg /ml associated with a favorable cervix (Ekman et al 1995)

A positive FFN was associated with significantly shorter delivery intervals than when a negative FFN result is obtained (Kiss et al.2000)

Ultrasound assessment of the cervix has been investigated as a way of predicting the likely outcome of induced labour as an alternative to clinical digital examination. Studies have explored possible relationships between cervical length, internal cervical OS shape and assessment of the angle between the cervical axis and the wall of the inferior segment of the uterus (Chandra et al.2001)

Electrical impedance measurements across the surface of the cervix using a 8mm tetrapolar pencil probe have been used to investigate correlations with clinical examination to assess cervical favorability (O'Connell et al 2003).

A statistically significant association was found with the resistivity and the favorability of the cervix Serum nitrite /nitrate levels also has been assayed in nullipara undergoing prostraglandin induction of labour and using multiple regression analyses significantly lower levels of each were found in woman who delivered within 15 hrs of labour induction compared with those delivering over a longer period (Facchinetti et al. 1998)

ANTOMY AND PHYSIOLOGY OF THE UTERINE CERVIX

The human uterine cervix is a complex and heterogeneous organ that undergoes extensive changes throughout gestation and parturition.[11] It is a unique valve responsible for keeping the fetus inside the uterus until the end of gestation and for its safe passage to the outside world during labor

The cervix is dominated by fibrous connective tissue. It is composed of an extracellular matrix consisting predominately of collagen with elastin and proteoglycans, and a cellular portion consisting of smooth muscle and fibroblasts, epithelium and blood vessels. The relative ratio of connective tissue

to smooth muscle is not uniformly distributed throughout the length of the cervix. The distal portion has a greater ratio of connective tissue to smooth muscle than the upper cervical portion closer to the myometrium.[12]

Extracellular Matrix:

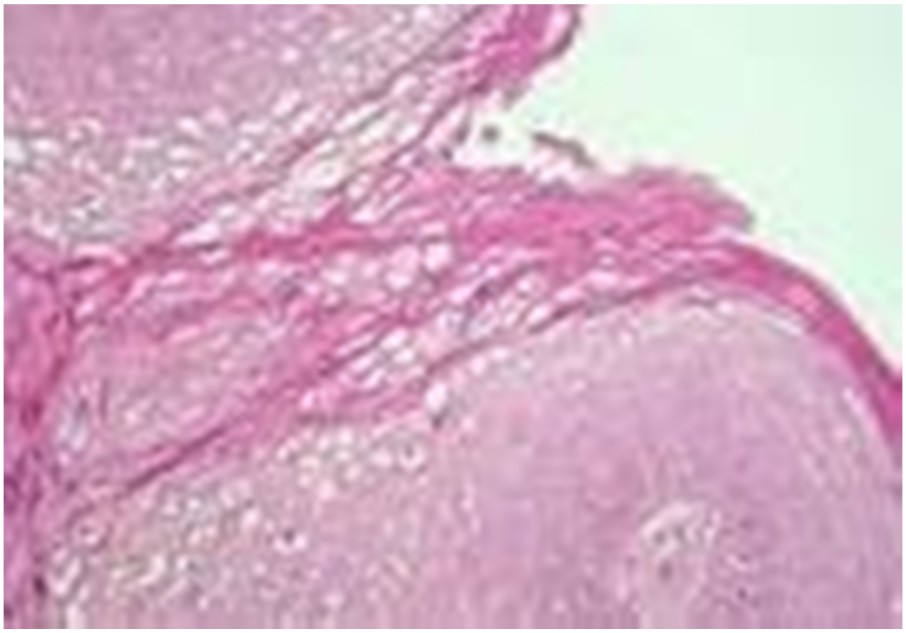
Collagen is the predominant component of the extracellular matrix. Cervical collagen consists of type I (70%) and type III (30%). [13] Collagens arranged as a triple helix. It can cross linked into fibrils, fibers, and bundles. Collagen fibers must be at least 20 μ m in length to maintain tensile strength[14] peptidyl lysine oxidase is the enzyme that cross links collagen. Copper and vitamin C are cofactors.

Another important molecule involved in collagen structure within the human cervix is the presence of a small molecular weight proteoglycan, decorin [15] cervical cells produce decorin during pregnancy. When the ratio of decorin to collagen increases, it causes a dispersal of collagen fibrils leading to disorganization of the collagen fibers.[16] Collagen is degraded by collagenases both intracellularly, to remove structurally defective procollagen to prevent the formation of weak structural collagen, and extracellularly, to slowly weaken the collagen matrix to allow delivery of the pregnancy.

Elastic Component:

Elastic fibrers are organized parallel to and between collagen fibers. They assemble in a band 20-30µ m thick.[17] These thin sheets are capable of being stretched in any direction. With mechanical stress, the elastin component can distend to twice its length to allow the cervix to dilate for parturition. The elastin fibers appear broken and fragmented compared with samples from women with full term pregnancies that revealed elastin oriented in a band like manner.[18]

ELASTICCOMPONENT



Cellular Component:

Smooth muscle cells and fibroblasts make up the cellular component of the human uterine cervix. Early in gestation, turnover of both smooth muscle and fibroblast is initiated. The cervix undergoes hyperplasia as these cells proliferate. As the pregnancy advances, physiologic cell death occurs. Decorin suppress the further cell proliferation, which accounts for further increases in decorin levels; a process that helps to disperse collagen fibrers. This disorganization of collagen then aids in an influx of water and aids in increasing the ability of the cervix to distend.[19]

CELLULARCOMPONENT

Elements Affecting Cervical Ripening:

The various elements implicated include decorin, hyaluronic acid, hormones, cytokines and proteases. These factors are responsible for increasing the water content in the cervix, decreasing the collagen concentration, and collagen restructure. Decorin is responsible to cause tight alignment of collagen fibrils and the ratio of decorin to collagen correlates with the softness of the cervix in a incerse manner.

The Second mechanism is enzymatic degradation of the extracellular matrix. Collagenases, Matrix metalloproteinases (MMP I & 8) which cleave the collagen helices and Elastases are the enzymes involved in this late restructuring of the cervix.

Hyaluronic acid has also been shown to stimulate the synthesis of proteolytic enzymes by cervical fibroblasts.[20] Hyaluronic acid level increases with cervical ripening and increase dramatically in the cervix with the onset of labour. It has got an important role in increasing the water content of the cervix at term. It also has a role in neovascularization, a process noted with cervical ripening. Hyaluronic acid increases the chemotactic response of neutrophils. [21]

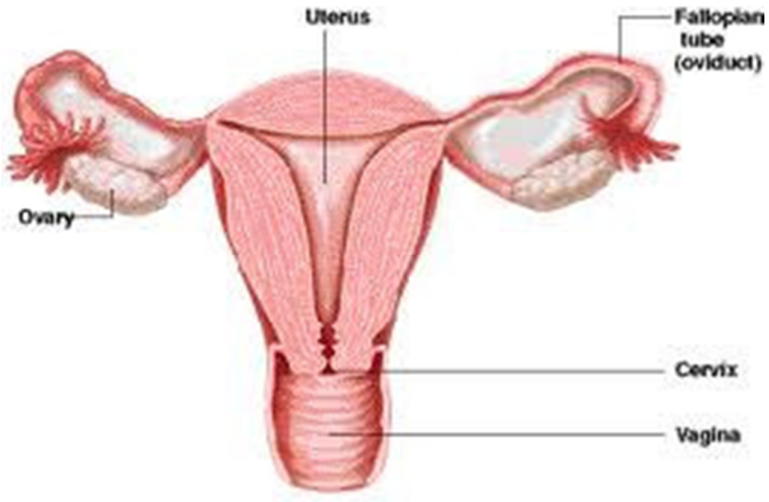
Human cervical connective tissue contains both estrogen and progesterone receptors. As term approaches, there is down regulation of both estrogen and progesterone receptors, which may be caused by increased turnover of the receptor proteins[22]. Estrogen and its precursors have been

shown to stimulate collagenase production in the pregnant human cervix.[23] Progesterone inhibit cervical tissue from producing intrleukin-8.

CERVIX – ANATOMY:

The cervix is about 5.0cm long and projects into the vagina to form the fornices. It has a supravaginal and an infravaginal part or portio vaginals. The supravaginal part is covered by peritoneum posteriorly. The ureter runs very close to the cervix and is about 1.2cm away from the supravaginal cervix. The cervix has a cervical canal which extends from the internal OS above to the external OS below. The external OS in a nullipara is a circular opening, whereas in a multiparous women it appears as a transverse slit, thus creating the anterior and posterior lips of the cervix.

CERVIX



Cervical length is normally distributed and remains relatively constant until the third trimester.[24] Heath found at 23 weeks a mean length of 38mm.[25] Iams found a mean length at 24 weeks of 35mm and at 28 weeks 34mm.[26] If funneling is present, the measurement should exclude the funnel and be taken from the funnel tip to the external OS Isthmus.[27]

It is the portion where the cervix joins the uterus,the area between the anatomical internal OS and the histological internal OS is called the isthmus and is of special obstetric significance as it develops into the lower uterine segment in pregnancy. The histological internal OS is the point at which the epithelium of the uterus changes to that of the cervix.

PRE INDUCTION CERVICAL ASSESSMENT:

The rate of labour progression relates to certain identifiable prelabour characteristics of the cervix. The validity of scoring systems for predicting the course of induced labors has been reported in terms of time from start of induction until onset of labor, and the rate of operative delivery.

In 1964, Bishop described a scoring system for determining a patient's suitability for elective induction of labor.[28] This pelvic score, which has become known as the Bishop score, was based on those factors that had been previously found to correlate with ripeness.

Parameters	Score			
	0	1	2	3
Cervical dilatation	Closed	1-2 cm	3-4 cm	5 cm
Length	3	2	1	0
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid position	Anterior	
Head station	-3	-2	-1,0	+1, +2

Modifiers:

Add 1 point to score for:

1. Preeclampsia
2. Each prior vaginal delivery

Subtract 1 point from score for:

1. Post dated pregnancy
2. Nulliparity
3. Premature or prolonged rupture of membranes. Total score is sum of all points for each parameter.

The meaning of the score:

- 7 or less: Do not attempt induction without ripening the cervix first.
- 9 or more: Favorable to attempt induction
- 12 or More: She is quite ready for labour or in early labour; a little encouragement should get her going.

CERVICAL EXAMIANTION

The degree of cervical effacement usually is expressed in terms of the length of the cervical canal compared with that of an uneffaced cervix. When the cervix becomes as thin as the adjacent lower uterine segment, it is completely, or 100% effaced. Cervical dilatation is determined by estimating the average diameter of the cervical opening by sweeping the examining finger from the margin of the cervical opening on one side to that on the opposite side. The diameter traversed is estimated in centimeters. The cervix is said to be dilated fully when the diameter measures 10cm, because the presenting part of a term – size new born usually can pass through a cervix this widely dilated.

The position of the cervix is determined by the relationship of the cervical OS to the fetal head and is categorized as posterior, mid position, or anterior: Along with position, the consistency of cervix is determined to be soft, firm, or intermediate between these two.

The level or station – of the presenting fetal part in the birth canal is described in relationship to the ischial spines, which are halfway between the pelvic inlet and pelvic outlet. When the lowermost portion of the presenting fetal part is at the level of the spines, it is designated as being at zero station. In 1989, the American College of Obstetricians and Gynecologists adopted the classification of station that divides the pelvis above and below the spines into fifths. Each fifth represents a centimeter above or below the

spines. Thus, as the presenting fetal part descents from the inlet toward the ischial spines, the designation is -5, -4, -3, -2, -1 then 0 stations. Below the spines, as the presenting fetal part descends, it passes +1, +2, +3, +4 and +5 stations to delivery. Station +5 corresponds to the fetal head being visible at the introitus. [29]

Modifications of the Bishop Score:

Modifications of the Bishop score were proposed in an effort to increase its predictability for successful induction and decrease morbidity rates associated with induction.

Burnett Modification of the Bishop score:

Burnett proposed a modified score system. This allocated a maximum score of 2 to each Bishop's five categories; yielding a total maximum score of 10, and considered effacement in terms of length. [30]

BURNETT MODIFICATION

Factors	**Score**		
	0	**1**	**2**
Dilatation (cm)	<1.5	1.5 – 3	>3
Station	-2 or higher	-1	0' or lower
Position	Posterior	Mid	Anterior
Head station	1.5 or more	Intermediate	0.5 or less
Consistency	Firm	Intermediate	Soft

Burnett considered a previous term birth and cephalic presentation to be prerequisites to induction of labor. He considered previous uterine surgery a contraindication to this procedure.

When patients had a score of 9 or 10 on this modified scale, Burnett found that all patients could be delivered within 4 hrs, most within 2hours. Additionally, 90% of patients with sores of 6 to 8 delivered within 6 hours. He found that the outcome of patients having scores less than 6 was unpredictable.[31]

Friedman et al [32] modified the Bishopscore in a different way. They evaluated 408 multiparas undergoing labor induction and found that the latent phase, but not the active phase, of the first stage of labor was inversely related to the preinduction cervical score. The factors considered in determining the Bishop score did not equally influences the length of the latent phase. They proposed that cervical dilation should be allocated twice the influence as of consistency, station, and effacement and four times that of position .

Fields system for Rating Readiness for induction [33]

Factor	Score		
	0	**1**	**2**
Timing of induction versus EDC (wks)	Uncertain or >3 previous	1-3 previous	Within1
Attitude toward induction	Objects or fears	Hesitates, accepts	Enthusiastic
Estimated fetal weight (gms)	<2,500	Uncertain	>2,500
Uterine tone on Palpation	Flaccid	Some tone	Firm, contraction
Softness of cervix	Firm	Some what soft	Soft
Effacement (%)	<80	80	>80
Position of cervix	Posterior	45o to vaginal axis	Toward vulva
Station of presenting part (cm)	-2 or higher	-1 to 0	+1 or lower
Dilation (cm)	0-1	2-3	>3
Recent vaginal discharge	No change	Increased	Blood tinged

The same group of investigators proposed two weighted scoring system based on these findings.[34] However, even in the authors own analysis, performance of neither of these weighted scoring systems was different enough from the raw Bishop score to be clinically significant. Weighted Bishop score proposed by Friedman et al.

Factors	Unweighted	Simple weighing	Complete weighting
Dilatation	0-3	x2	X4
Effacement	0-3	X1	X2
Station	0-3	X1	X2
Consistency	0-2	X1	X2
Position	0-2	X0	X1
Range of scores	0-13	0-14	0-30

Evaluation of the Bishop score:

Several groups have reported evaluations of the Bishop score. In 1977, Harrison et al[35] evaluated Bishop score of patients at 36 weeks gestation and again at 40 weeks gestation. They found a significant increase in scores during the last month of pregnancy. They also confirmed the association between the Bishop score and the duration of induced labor. Patients with a score of 7 or more delivered in less than 9 hours 87% of the time, whereas patients having score of 4 or less delivered within this interval only 44% of the time.

Lange et al [36] in 1982, evaluated 1,189 patients who underwent successful induction of labor for obstetric or medical indications. They confirmed that the Bishop score, as used in Denmark with effacement expressed as centimeters of cervical length correlated well with the likelihood of successful induction. They found that cervical dilation was at least twice as important as the other factors considered in the Bishop score.

Based on these findings, Lange et al proposed another modification of Bishop's scoring system.

Pelvic score proposed by Lange et al

Factors	Score				Multiply By
	0	1	2	3	
Dilation (cm)	0	1-2	3-4	>4	X2
Length (cm)	3	2	1	0	X1
Station (cm)	-3	-2	-1 or 0	+1 / +2	X1

This simpler scoring system predicted successful induction equally as well as the Bishop score.

A study by Hughey et al [37] evaluated the comparative performance of the scoring system proposed by Bishop, Fields, Burnett and Friedman. The increased likelihood of successful induction with increasing scores was confirmed for all of these system. It is interesting that these authors suggested adding 'modifiers' to whichever scoring system was used in an attempt to optimize the system's prediction accuracy.

They proposed adding points for preeclampsia, each previous delivery, and elective induction. Points were substracted for premature rupture of membranes, postdatism or nulliparity. In their study, these modification, improved the accuracy of all scoring systems.

ULTRASOUND ASSESSMENT OF THE CERVIX

In more recent years, ultrasound assessment of preinduction cervical characterists has been evaluated. In 1986, O'Leary and Ferrell 38 proposed what they called as 'semi quantitative' ultrasound scoring system and evaluated this system against the modified Bishop score. This scoring system, which apparently used trans abdominal ultrasound, evaluated the thickness and contour of the lower uterine segment, the length and dilation of the cervix, and the station of the presenting part. The authors found that the ultrasound scoring system correlated well with the modified Bishop score and that a favorable result with either digital or ultrasound assessment was associated with a high likelihood of successful induction.

ULTRASOUND MECHINE WITH TRANS VAGINAL PROBE

TRANS ABDOMINAL CERVICAL MEASUREMENT

Ultrasound assessment of the cervix was initially Trans abdominal, but specific disadvantages led to a preference for the transvaginal examination.[39]

1. Trans abdominal ultrasound requires filling the bladder to assess the cervix adequately, but this may spuriously lengthen the cervix by opposing the anterior and posterior lower uterine segments, concealing cervical shortening or funneling. In contrast, transvaginal ultrasound is performed with the bladder empty.[40]

2. Trans abdominal resolution is hampered significantly by maternal obesity, shadowing from fetal parts and the need for lower frequently transducers.

3. The long distance from the probe to the cervix does not allow for clear visualization of the cervix.[41]

TRANS PERINEAL ULTRASOUND

Transperineal ultrasound also known as translabial. This technique involves having the women lie on the table with the hips and knees flexed, while a gloved transducer is positioned on the perineum in a sagittal orientation between the patient's labia majora. This technique is not impaired by obstruction from fetal parts, and does not require bladder filling, achieving close to 100% visualization.

Advantages:

1. The transducer is closer to the cervix; but does not enter the vagina (so no pressure can be exerted on the cervix).
2. It does not require an additional transducer.
3. It is well accepted by pregnant women.

Drawbacks:

1. Gas shadow in the rectum can hamper visualization of the cervix, especially the external OS.
2. This technique is difficult to master, probably because of the poor visualization usually achieved compared with transvaginal ultrasound.

TRANS VAGINAL ULTRASOUND MEASUREMENT

The First studies of the human cervix using trans vaginal ultrasound also date back to the 1980s. this technique share the advantages of translabial ultrasound but the probe is even closer the cervix, and the problem of obscuring bowel gas is eliminated. It has thus become the preferred, gold standard method of evaluating the cervix in most clinical settings.

Current recommendations for the performance of TVU of the cervix are as follows: [42]

1. Have the patient empty her bladder;
2. Prepare the clean probe covered by a condom;
3. Insert the probe (probe can be inserted by patents for more comfort).
4. Place the probe in the anterior fornix of the vagina

5. Obtain a sagittal view of the cervix, with the long axis view of echogenic endocervical mucosa along the length of the canal.
6. Withdraw the probe until the image is blurred and reapply just enough pressure to restore the image (avoid excessive pressure on the cervix which can elongate it).
7. Enlarge the image so that the cervix occupies at least 2/3 of the image, and external and internal OS are well seen;
8. Measure the cervical length from the internal to the external OS along the endocervical canal.
9. Obtain at least 3 measurements, and record the shortest best measurement in millimeters;
10. Apply transfundal pressure for 15 seconds and record any changes in cervical length or funneling.

For Best Results:

1. The internal OS should be flat or at an isosceles angle with respect to the uterus and the external OS should be visible and appear symmetric.
2. The whole length of the cervix should be visualized, so that the endocervical canal is visible from the internal to external OS.
3. A symmetric image of the external OS should be obtained, so that the distance from the surface of the posterior lip to the cervical canal should be equal to the distance from the surface of the anterior lip to the cervical canal.

4. There should not be any increased echogenicity in the cervix (a sign of excessive pressure)[43]

Although TVU of the cervix is usually straight forward there is some anatomic or technical difficulty encountered in about one forth of patients. [44]

Anatomic:

- Focal myometrial contraction: may obscure the internal OS and make the cervix appear longer than it is:
- Endocervical mucus or polyps: may appear to separate the anterior and posterior borders of the endocervical canal and make the cervix measure shorter than it is.
- Rapid cervical change (dynamic cervix): CL may fluctuate during an examination. This is itself a risk factor for preterm delivery, especially if the shortest cervical measurement is below 15mm.

Technical:

- Vaginal probe orientation: because the cervical canal has width (usually less than 1 cm in the axial plane) the manual examination may show a greater dilatation than the TVU CL in just the sagittal plane. In addition, in experienced hands, it is possible to obtain several diagnonal angles through the cervix all giving a shorter CL than the true sagittal plane.

- Pressure distortion: even minimal pressure on the cervix falsely elongates the CL measurement. Increased echogenicity within the cervix or just posterior to it usually indicates excessive probe pressure.

Normal Cervical length by ultrasound:

Ultrasound measurement of the cervical canal in the second and early third trimester has been reported to range from 10 to 50 mm. Iams et al45 measured cervical length at 24 and 28 weeks gestation in nearly 3000 women not selected for risk of preterm delivery. At 24 weeks mean cervical length in nulliparous women were 34 ± 7.8mm and 36 ± 8.4mm in parous women. At 28 weeks, the cervix shortened slightly to 32.6 ± 8.1mm in nulliparous women and 34.5 ± 8.1mm in parous women. The tenth percentiles cervical length measurement at 24 weeks was found to be 25 mm and this increased the risk of preterm delivery six fold.

Other uses of ultrasound Cervical Assessment:

Prediction of Preterm Birth

Studies that have evaluated the usefulness of TVU for predicting PTB, found that the shorter the cervix, the higher the risk of PTB. Using different cut-offs for CL ranging from 15mm to 34mm, the positive predictive values ranged from 6% to 44%. 46 This relatively low value is likely due at least in part to the low incidence of PTB in these studies (0.8% - 15%).

A recent study well designed blinded multicenter study of Maternal Fetal Medicine Units Network of the National Institute of Child Health and Human Development on TVU in patients with a history of PTB <23 weeks demonstrated that the best predictive accuracy was achieved with serial TVUs, and including the shortest cervix ever after spontaneous or transfundal pressure elicited changes. The sensitivity and positive predictive value reached 69% and 55% respectively. [47]

Twins:

In a preterm prediction study in twin gestation, Goldenberg found that a cervical length ≤25mm at 24 weeks gestation to be the best of all the predictors of PTB that they evaluated, including fetal fibronectin and bacterial vaginosis.[48] Compared with singleton pregnancies, twin pregnancies that deliver at term have been shown to have a similar TVU CL at 14 to 19 weeks; but have a progressively much shorter cervix starting after 20 weeks gestaton.[49] Since cervical shortening occurs after 20 weeks gestation even in twin pregnancies destined to delivery at term, sonographic examination of the cervix before 20-24 weeks may lead to better prediction of PTB. A recent study found that the predictive value of sonographic CL determination in twins between 24-34 weeks gestation was low.[50]

Women with Cerclage:

TVU of the cervix has been evaluated in patients with prophylactic, therapeutic or emergent cerclage in place. Most studies have shown that transvaginal cerclage is placed in the middle part of the cervix in a majority of cases.[51] Evaluation of pre-and post – cerclage TVU CL has shown that CL usually increases post cerclage, and that an increase in CL is associated with a higher rate of term delivery.[52]

Several studies have evaluated the accuracy of TVU for predicting PTB in patients with cerclage.[53] These studies show that TVU cervical parameters are predictive of PTB CL <25mm and upper cervix (the closed portion above the cerclage) <10mm are probably the two best predictive parameters.

Evaluation of patients with suspected preterm labor:

TVU of the cervix has been studied extensively as a predictor of PTB in patients with symptoms of PTL. While inclusion criteria in these studies were all slightly different, all showed a statistically significant predictive accuracy of TVU for PTB. Zalar54 reported a decrease in incidence of birth weight <2,500gms when TVU of the cervix was used to triage patients to bed rest and tocolysis, compared with historic controls. Rageth [55] showed that using TVU in symptomatic patients for management could decrease the incidence of hospitalization and costs, but did not decrease PTB.

Predicting latency in PPROM:

Three studies have examined the utility of TVU of the cervix in patients with preterm premature rupture of membranes (PPROM). Carlan [56] demonstrated in a randomized trial the safety of performing TVU in this group. In patients studied between 24-34 weeks, he found that the latency was 2 days shorter if the CL was $\leq$ 30 mm. Rizzo [57] studied 92 women with PPROM between 24 and 32 weeks and showed that a CL $\leq$ 20 mm was associated with a latency of 2 days versus 6 days if the CL was >20mm.

CERVICAL RIPENING

Cervical ripening is a chronic process, which begins within the first trimester of pregnancy and progressively proceeds until term, and is usually described as softening, effacement and dilation of the cervix. Softening must be considered a vital process because effacement and dilation cannot occur without remodeling of the cervix during the softening phase. Effacement and dilation are often associated with or contributed to uterine contractions, but it is evident that softening occurs independent of contractions. Throughout most of gestation the cervix remains rigid and closed to secure the products of conception. A dramatic functional shift occurs during parturition as it dilates through a cervical destructive process. The cascade responsible for the process of cervical ripening, and which finally enables uterine contractions to efface and dilate the cervix, is still not fully understood.

Studies in cervical resistance and light induced Fluorescence (LIF) have measured these changes in rats. [58]

Many studies show that hormones seem to control cervical ripening although the mechanisms and effects on each step in ripening are not clear. Because antiprogestins induce cervical ripening, this process seems to be controlled at least in part by hormones including progesterone and estrogen [59] relaxin and androgens.[60] The gene is involved in androgen production, and the parturition defect can be overcome by treatment with 5α reduced androgens. The enzyme plays an essential role in progesterone catabolism in the cervix inhibiting the conversion of testosterone to dihydrotestosterone resulting in localized failure of progesterone withdrawal. The physiologic decrease in the concentration of progesterone during the third trimester of pregnancy initiates a cascade that is analogous to an inflammatory response with influx of polymorphonuclear cells 61 and release of matrix – metalloproteinases into the cervical stroma, culminating in the degradation is mostly probably due to decreased sensitivity of the hormone receptor.

The nervous system has significant involvement in the process of reproduction and could also be involved in cervical ripening. Sensory, sympathetic and para sympathetic fibers are numerous in the cervix [62]. The seonsory component largely comes from the pelvic nerves L6- S1 dorsal root gandglia and terminates in the cervix as unmyelinated, small, capsaisin – sensitive sensory neurons. These synthesize neurotransmitters such as

vasoactive neuropeptides, calcitonin gene related peptide, substance P, and secretoneurin, which are locally released n the cervix and act through their receptors to induce inflammatory like cervical changes with vasodilatation, vascular leakage and plasma and leukocyte extravasations.

Very little is known about how cervical ripening can be prevented or inhibited. Recently, it has been found that oral administration of a platelet activating factor receptor antagonist in rats significantly increases the duration of parturition [63] platelet activating factor antagonist WEB – 2170 effectively inhibits preterm cervical ripening induced by lipopolysaccharides in an in vivo animal model.

Measurements of Cervical Softening:

Evaluation of the first common step, cervical softening, has been hypothesized to be useful for the early evaluation of alternations in cervical ripening either spontaneously occurring or medically induced. Collascope is a device, used for quantitative estimation of cervical ripening. It uses the light induced fluorescence of cross linked collagen to permit the attending physician to differentiate between the labour versus the non labour state of the cervix.

Fluorescence Spectroscopy of Collagen:

Fluorescence spectroscopy can reveal molecular and physical states.[64] Fluorescence spectra offer important details on the structure and dynamics of macromolecules and their location at microscopic levels. It has

been used to examine collagen content of a variety of tissues including cancers.[65]

Cervical LIF (Light Induced Fluorescence)

One study involving cervical collagen was conducted to investigate gestational changes of cervical LIF, an index for cross linked collagen, and to estimate whether LIF correlates with the time – to – delivery interval and is predictive of delivery within 24 hours.[66] Cervical LIF was obtained noninvasively by using the collascope. Patients who delivered within less than 24 hours of measurement had significantly lower LIF than those who delivered more than 24 hours later.

INDUCTION OF LABOR:

The goal of induction labor is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor. Induction of labor has merit as a therapeutic option when the benefits of expeditious delivery outweigh the risk of continuing the pregnancy. The benefits of labor induction must be weighed against the potential maternal and fetal risks associated with this procedure.[67] The goal of cervical ripening is to facilitate the process of cervical softening, thinning and dilating with resultant reduction in the rate of failed induction and induction to delivery time. Cervical remodeling is a critical component of normal parturition. Observed changes not only include collagen breakdown and rearrangement but also changes in the

glycosaminoglycans, increased production of cytokines and white blood cell infiltration.[68]

Labor Induction Terminology:

At a 2008 workshop sponsored by American College of Obstetricians and Gynecologists for Maternal Fetal Medicine on Intrapartum electronic FHR monitoring renewed the existing classification systems for FHR patterns[69] in particular, it was determine that the terms hyperstimulation and hypercontractility should be abandoned. It was recommended that the term tachysystole, with or without corresponding FHR decelerations, be used instead.

Uterine Contractions:

Uterine contractions are quantified as the number of contractions present in a 10 minute window, averaged over 30 minutes. Contraction frequency alone is a partial assessment of uterine activity. Other factors such as duration, intensity, and relaxation time between contractions are equally important in clinical practice. The following represents terminology to describe uterine activity.

- Normal: Five contractions or less in 10 minutes, averaged over a 30 minute window.
- Tachsytole: More than 5 contractions in 10 minutes, averaged over a 30 minute window.

Listed characteristics of uterine contractions:

1. Tachysystole should always be qualified as to the presence or absence of associated FHRdecelerations.
2. The term tachysystole applies to both spontaneous and stimulated labor. The clinical response to tachysystole may differ depending on whether contractions are spontaneous or stimulated.

ACOG Recommendations for Indication of Labor Induction:

- AbruptioN placenta
- Chorioamnionitis
- Fetal demise
- Gestational hypertension
- Preeclampsia, eclampsia
- Premature rupture of membranes
- Post term pregnancy
- Maternal medical conditions. (Diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension, antiphospholipid syndrome).
- Fetal compromise (eg: severe fetal growth restriction, isoimmunization, oligohydramnios).

Contraindications of Labor Induction:

- Vasa previa or complete placenta previa
- Transverse fetal lie
- Umbilical cord prolapse
- Previous classical cesarean delivery
- Active genital herpes infection.
- Previous myomectomy entering the endometrial cavity.

Criteria should be met before the cervical ripening:

Assessment of gestational age and consideration of any potential risk to the mother or fetus are of paramount importance for appropriate evaluation and counseling before initiating induction. The patient should be counseled regarding the indications for induction, the agents and methods of labor stimulation and the possible need for repeat induction or cesarean delivery. Labor progression differs significantly for women with an elective induction of labor compared with women who have spontaneous onset of labor.[70] Allowing at least 12-18 hours of latent labor before diagnosing a failed induction may reduce the risk of cesarean delivery.[71]

Cervical ripening with PGE2:

The first use of a Prostaglandin for the induction of labor was reported by Karim et al in 1968. the PG used was PGF2α. PGE2 and PGF2α both

stimulate contractions of the pregnant uterus and cause similar side effects in terms of nausea, vomiting and diarrhea, and they have a number of opposite actions on different organ systems.[72] PGE2 is a vasodilator, it causes hyperthermia. PGF2α is a vasoconstrictor. PGE2 is 5o to 10 times more potent than PGF2α on the pregnant uterus. PGE2 is available in solution, oral tablets, vaginal tablets, vaginal pessaries, gels and slow release vaginal inserts containing different amounts of PGE2. PGE2 in gel form is available as 0.5mg dose for endocervical application and 1 or 2 mg doses for vaginal use (prostin E2), where as vaginal pessaries exist in 3 and 20mg formulations.

Routes of PGE2 administration:

Intravenous PGE2

Systemic reviews of the literature on intravenous infusion of PGE2, the earliest and now abandoned route of administration, indicated that it offered no advantages over intravenous oxytocin.[73] The main problem was the small margin between doses that stimulated contractions and those that produced hyper stimulation and a large differential in cost for no benefit.[74] The most bothersome, in terms of non uterine effects, was hyperthermia because of the difficulty of differentiating this PGE2 effect on thermoregulation from signs of chorioamnionitis, particularly as PGE2 and some PG analogs also stimulate leucocytosis.

Extra amniotic PGE2:

Initially administered as an extra amniotic infusion was the method, used when ripening effects of PGE2 on the uterine cervix was first identified. This was later replaced by insertion in a viscous gel.[75] By inserting endocervical gel preparations well above the internal OS, which partially explains the large differences in uterine response observed among studies using the same endocervical preparations.[76]

Oral PGE2:

Oral administration of PGE2 became popular in several European Countries in the 1970s predominantly because of the freedom of movement that it offered compared with an intravenous line. It was thought to be less dependent on concomitant amniotomy to enhance its effectiveness that induction with oxytocin. The induction trials comparing oral PGE2 with intravenous oxytocin with amniotomy, in both arms, in neither arm, or in the oxytocin arm only, showed little difference between the methods compared except for a reduction in the rate of operative delivery, probably related to ambulation, that just reached statistical significance.[77] The total amount of PGE2 administered, mostly at hourly intervals, was higher than that needed with any other route of administration and vomiting was common with repeat episodes occurring in upto 10% women depending on the doses used.[78]

Endocervical PGE2:

A large number of studies has been conducted with endocervical gels either locally prepared or commercially available as prepedil or cerviprost, the latter both containing 0.5mg PGE2 but in different gels. The endocervical approach is sometimes referred to as intracervical, a notion that should be reserved for injection into the body of the cervix, a procedure that has been used to reduce cervical resistance to mechanical dilatation both outside pregnancy and in early pregnancy, but also for induction of labor in late pregnancy.[79] It initiate labor and abolish the need for further induction in more than 40% of women and reduce the risk of failed induction.[80]

The use of oxytocin alone is more likely to result in failed induction and absence of vaginal birth within a reasonable interval than the use of endocervical PGE2 alone or pretreatment with endocervical PGE2.[81]

Hyperstimulation is an issue that has drawn considerable attention probably more so with endocervical PGE2 that with other routes of PGE2 administration.

Vaginal PGE2:

Initially assessed explicitly for ripening the cervix in nulliparous women,[82] the use of vaginal PGE2 soon spread to both ripening and induction. Current dose ranges from 1 to 3mg per dose. A trial induced 260 nulliparous and parous women all with Bishop score of 6 or more, women in the amniotromy arm received oxytocin after 4 hour if not in labor, whereas women in the PGE2 group had amniotomy after 4 hours and oxytocin another 2 hours later, if not in established labor. Despite including only women with a favourable cervix, the need for oxytocin supplementation was 3 times higher in amniotomy group (44% vs 15%). Rates of pyrexia and epidural analgesia in the amniotomy group were twice those with PGE2, with no cases of hyperstimulation and no differences in other outcomes including cesarean section (4.2%) between the 2 treatment regimens.[83] This trial is included in a Cochrane systematic review of amniotomy for induction of labor, which comments that the time allowed for amniotomy to work on its own, without the secondary intervention may have been too short.[84]

FAILED LABOR INDUCTION:

Definition: Failure to achieve dilation ≥4 cm after trial of oxytocin to a maximum of 20 mu/min.[85]

- Failure to enter the active phase of labor within 12 hours after IOL was begun [86] and failure to enter the active phase of labor (Bishop score >8) after 24 hours.[87]
- Adequate contractions for 2 hours without cervical change.[88]
- Failed induction occurred when painful, regular contractions with cervical change were not achieved and the patient was delivered by cesarean with failed induction.[89]
- Failure to achieve the active phase after a maximum of 12 hour of oxytocin administration.[90]
- Failure to deliver within 24 hours of induction[91]

Components of Definition:

From Friedman's studies, in the most general sense, induction failure can be best characterized by the failure to transition from the latent to the active phase of labor. Because the duration of the active phase is the same or shorter in induced compared to spontaneous labors.[92] We would argue that the criteria by which this transition can be judged to have occurred might plausibly depend on the combination of labor duration cervical dilation and uterine activity.

Labor Duration:

Peisner and rosen[93] studied 2479 women admitted with a cervical dilation of <5cm of the factors analyzed, cervical dilation on admission was the most important determinant of latent phase duration; with a mean latent phase

of a and a half hours for those dilated 0 to 2cm on admission. 3% of women studied had a latent phase longer than 20 hours. Admitting cervical dilation did not predict those at risk for latent phase prolongation.

Those who begin their induction with a Bishop score of <6 progress more slowly than women in spontaneous labor. As the length of the latent phase increases, the risk of adverse maternal and neonatal outcomes rises.[95]

Cervical Dilation:

Friedman defined the start of the active phase as the point along the labor curve when the slops begins to change. Peisner and Rosen in a prospective descriptive study of 1060 nulliparus and 639 parous women attempted to define the transition from latent to active phase by cervical dilatation. Women enrolled in the study presented in spontaneous labor and were dilated 4 cm or less. Entry into the active phase of labor was demarcated by a rate of cervical change of at least 1.2cm/hour. Patients with documented labor dystocia, whose transition to the active phase was difficult to pinpoint. There were 727 cases of either an active phase protraction or arrest. A 4cm cutoff with 90% effacement or a 5cm cut off regardless of effacement would capture the majority of women who have entered the active phase during labor induction.

Uterine activity:

In 1950 [96], Caldeyro-Barcia and his colleagues devised a novel method by which to measure intrauterine pressure. They inserted a thin polyethylene catheter into the amniotic sac through the anterior abdominal wall. The device was designed to record changes in the amniotic fluid pressure that arose as a result of uterine contractions. A Montevideo Unit (MU) was a measure of uterine activity that was the product of the intensity (amplitude) of each contraction and the frequency (number of contractions in 10 min). Caldeyro-Barcia illustrated that before 30 weeks of gestation the uterus maintained a resting tone of 20 mmHg. As the pregnancy progressed, the uterus becomes more responsive to oxytocin. A very small uterine contractions were characteristic and these contractions typically remained localized.

After 30 weeks, contractions were noted to increase in intensity, frequency and coordination. The beginning of labor is usually characterized by uterine activity between 80 and 120MU. Uterine coordination is important with the strongest portion of the contraction at the fundus. From there, it self propagates to the lower uterine segment. In normal labor uterine activity ranges between 75 and 375 MU.

The other most widely used method [97] is the uterine activity integral. The uterine activity integral incorporates measures of contraction frequency, duration and strength in its calculation. It is the integral of the pressure above baseline tone with time and is taken over a period of 15 minutes its units are kilo Pascal second (kPas). Mean active pressure is the most important variable in determine the rate of cervical dilation.

Materials and Methods

MATERIALS AND METHODS

STUDY DESIGN – Prospective Observational study

SAMPLE SIZE AND SOURCE OF DATA

100 primi gravida with gestational age ranging between 37-42 weeks who are admitted for labour induction under Obstetrics and Gynecology in Govt. Kasturba Gandhi Hospital, Madras Medical College, Chennai.

A minimum sample size of 100 is planned.

DURATION OF STUDY

1st March 2014 to 1st March 2015

INCLUSION CRITERIA

1. Nulliparous patients
2. Singleton pregnancy
3. Live fetus with vertex presentation
4. Intact amniotic membranes
5. Gestational age between 37-42 weeks
6. Reassuring NST pattern before induction
7. No contraindications for vaginal delivery
8. Patients who are willing to give consent for the study
9. Bishop score ≤ 6

EXCLUSION CRITERIA

1. Vaginal bleeding
2. Allergic to prostaglandins
3. Patients in active phase of labour
4. History of uterine surgery like previous LSCS, myomectomy
5. Presence of severe maternal or fetal compromise such as Severe PIH, Severe IUGR, Cardiac disease etc.

METHOD OF COLLECTION OF DATA

All patients who are willing to participate in this study will be included in the study baseline characters such as age, gestational age at induction & indication for induction are noted.

After informed consent is obtained, Transvaginal ultrasonographic measurement of cervical length is performed with the standard longitudinal view of the cervix while the patient's bladder is empty. GE VOLUSON 730 PRO TVS Probe IC5-9 H instruments with 5-9 MHz is using to measure the cervical length. Cervical length is measured by keeping the proble 3cm away from the posterior fornix. The cervical length is defined as the length between the internal and external OS.

After sonography the Bishop Score is determine by the digital examination by the resident physician responsible for the induction. Physicians were masked to the cervical length measurement.

Induction of labour is carried out according to the standard protocol of our hospital. Prostaglandin E2 gel is inserted into the cervical canal within 1 hour of cervical assessment. The patient is reassessed after 12 hours. If she did not exhibit regular uterine contractions and cervical change, a second dose of PG E2 is administrate intracervically. Maximum of 3 doses can be repeated. Subsequent dose is withheld if;

a) The patient is in active labour
b) Rapture of membrane
c) If cervical effacement >60% and OS ≥ 3 cm.
d) Regular uterine contractions 2-3 in 10 minutes.

Augmentation of labour is done as per labour room protocol.

Active phase of labour is diagnosed as 3-4 contractions in every 10 minutes, each lasting for 45 to 60 seconds. And the cervix is dilated ≥3cm and the effacement of cervix is 80% or greater. Successful induction of labour is defined as active labour occurring at the end of induction protocol (12 hrs from the last dose)

Failed induction is defined as an inability to achieve the active phase of labour corresponding to cervical dilatation of ≥3 cm within 12 hours from the last dose of PG E2.

Failure to progress is defined as no cervical dilation during the active phase of labour for the last 2 hours or no descent of the fetus' head during the second stage of labour for at least 1 hour despite adequate uterine contractions. This is considered as an indication for cesarean delivery for failure to progress.

Primary outcome measures assessed are

1. Induction to delivery interval < 24 hrs

Secondary outcome measures assessed are:

1. Induction – Active phase interval < 12hrs
2. Number of vaginal deliveries <48 hrs

Observation and Results

RESULTS

Hundred primigravida with gestational age between 37-42wks who are admitted for induction of labour were enrolled in the study. Demographic variables (age distribution, gestational age & indication for induction) are summarized.

TABLE 1 : AGE DISTRIBUTION WOMEN

AGE IN YEARS	NUMBER (%)
15-20	33 (33%)
21-25	49 (49%)
26-30	17 (17%)
31-35	1 (1%)
TOTAL	100 (100%)

FIGURE 1 : AGE DISTRIBUTION WOMEN

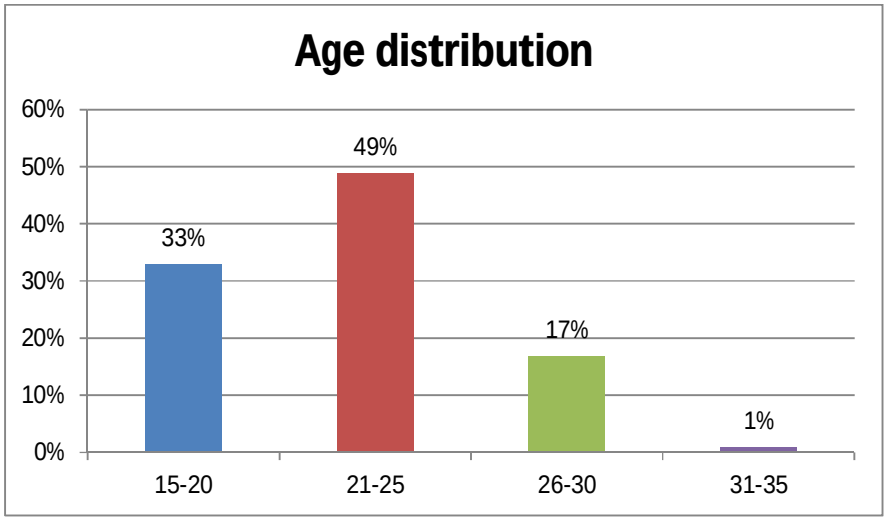


TABLE 2 : DISRIBUTION OF GESTATIONAL AGE

STUDY PARAMETER	GESTATIONAL AGE IN DAYS MEAN ± SD	Independent t test
GESTATIONAL AGE BY LMP	273.28± 8.172(250- 290)	t= 7.981*
GESTATIONAL AGE BY USG	262.50 ±10.755(238- 287)	

P<0.001

GESTATIONAL AGE BY LMP & GESTATIONAL AGE BY USG was significantly different.

TABLE 3: INDICATION FOR INDUCTION

INDICATION	Number (%)
POST DATISM	23 (23%)
MILD P I H	18 (18%)
PROLONGED LATENT PHASE	50 (50%)
DECREASED A F I <8CM	7 (7%)
DECREASED FETAL MOVEMENTS	2 (2%)
TOTAL	100 (100%)

FIGURE 2 : INDICATION FOR INDUCTION

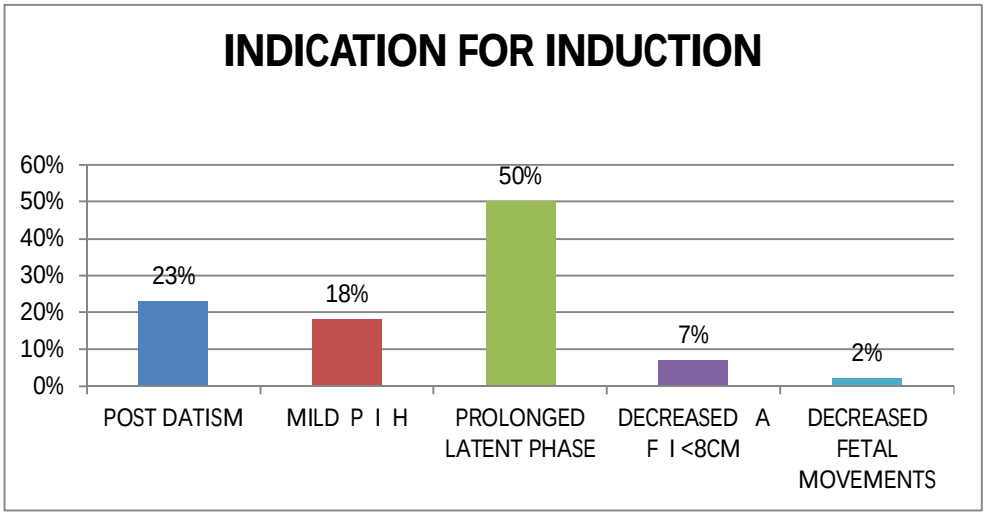


TABLE 4 : BISHOP SCORE TOTAL

BISHOP SCORE	Number (%)
1	4 (4%)
2	7 (7%)
3	17 (17%)
4	20 (20%)
5	26 (26%)

FITURE 3 : BISHOP SCORE TOTAL

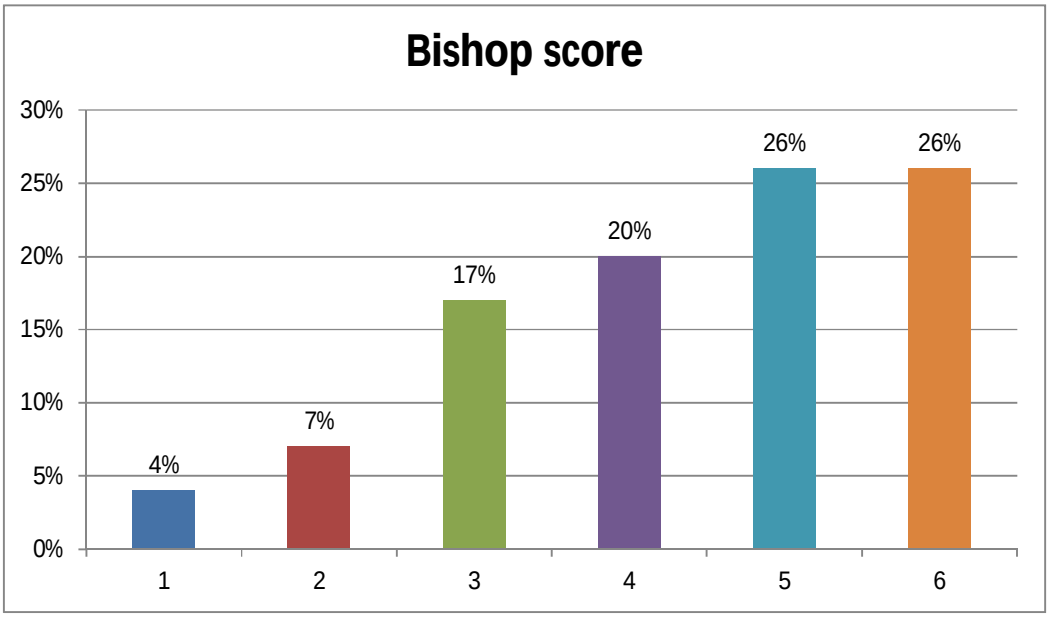
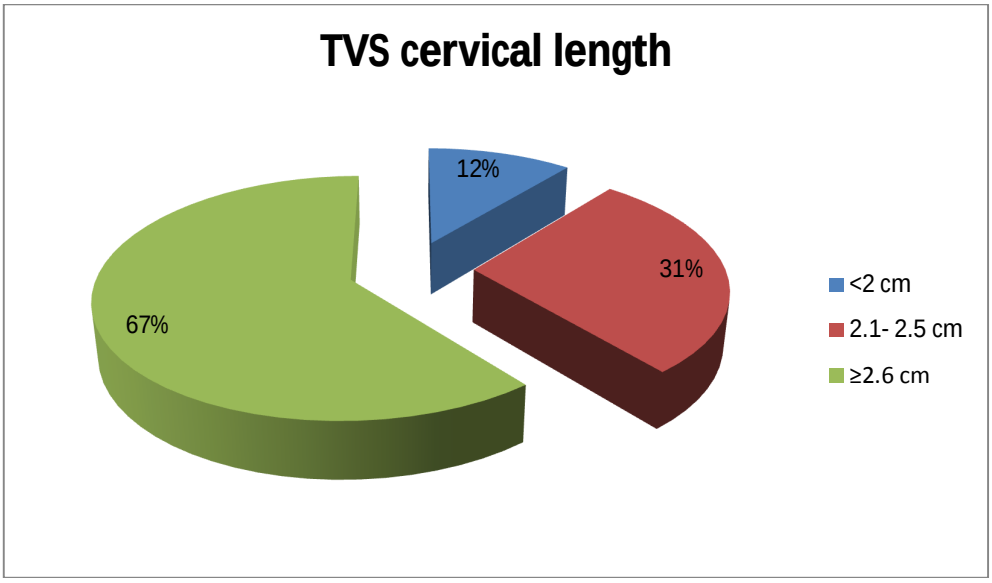


TABLE 5 : TRANS VAGINAL CERVICAL LENGTH

TVS cervical length In cm	NUMBER (%)
<2 cm	12 (12%)
2.1- 2.5 cm	31 (31%)

FIGURE 4 : TRANS VAGINAL CERVICAL LENGTH

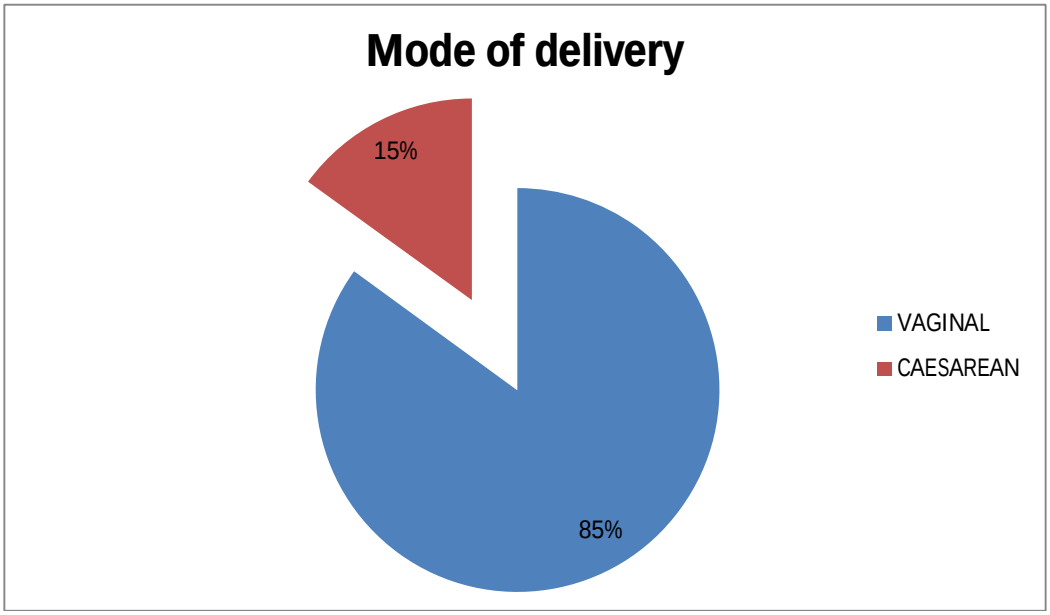


Women with trans vaginal cervical length <2cm were 12%, 31% of women were with cervical length between 2.1- 2.5cm and 67% were with cervical length of ≥ 2.6cm.

TABLE 6 : MODE OF DELIVERY

MODE OF DELIVERY	NUMBER (%)
VAGINAL	85 (85%)
CAESAREAN	15 (15%)

FIGUR E : MODE OF DELIVERY



Vaginal delivery occurred in 85% of women and in 74% of these, delivery was within 24hrs of induction. There were 15%deliveries by caesarean section.

Age * Mode_of_delivery Crosstabulation			Mode_of_deivery		Total
			Vaginal	LSCS	
Age	15-20yrs	Count	32	1	33
		% within Mode_of_deivery	37.6%	6.7%	33.0%
	21-25yrs	Count	40	9	49
		% within Mode_of_deivery	47.1%	60.0%	49.0%
	26-30 yrs	Count	12	5	17
		% within Mode_of_deivery	14.1%	33.3%	17.0%
	31-35 yrs	Count	1	0	1
		% within Mode_of_deivery	1.2%	0.0%	1.0%
Total		Count	85	15	100
		% within Mode_of_deivery	100.0%	100.0%	100.0%

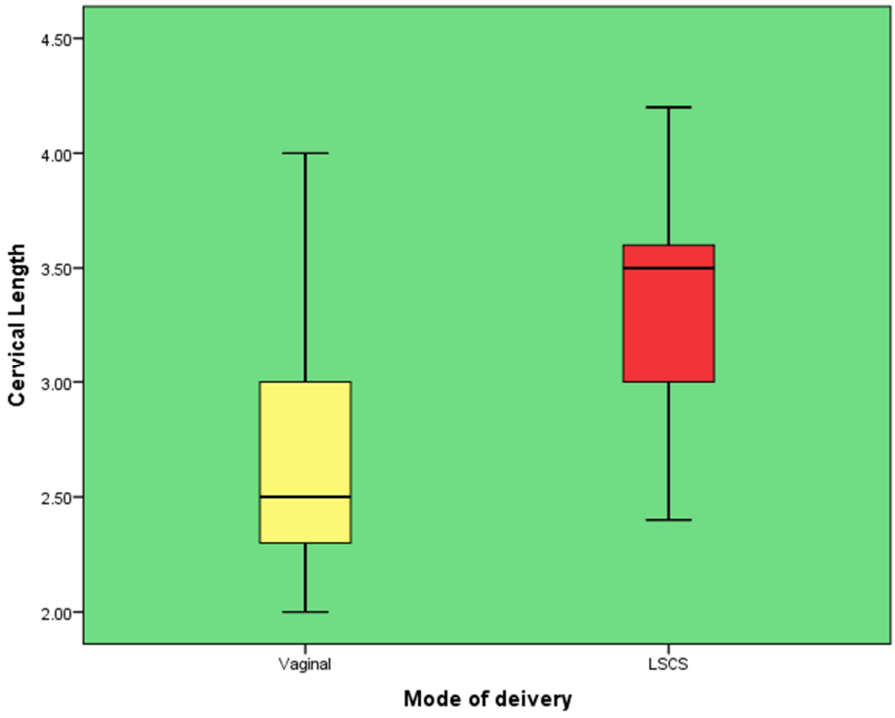
Chi square 7.090 p>0.05 (0.07) non significant

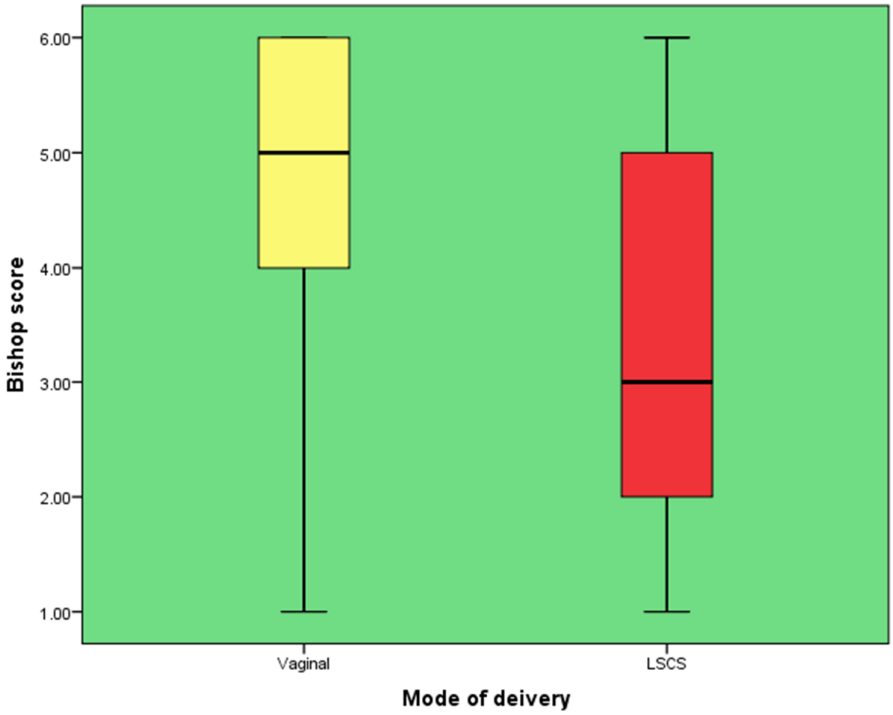
Crosstab			bishop score		Total
			<4	>=4	
Age	15-20yrs	Count	7	26	33
		% within bishop score	25.9%	35.6%	33.0%
	21-25yrs	Count	11	38	49
		% within bishop score	40.7%	52.1%	49.0%
	26-30 yrs	Count	9	8	17
		% within bishop score	33.3%	11.0%	17.0%
	31-35 yrs	Count	0	1	1
		% within bishop score	0.0%	1.4%	1.0%
Total		Count	27	73	100
		% within bishop score	100.0%	100.0%	100.0%

Chi square 7.250 p>0.05 (0.06) non significant

Comparison of Bishop and Cervical Length for Mode of delivery

Group Statistics						
	Mode_of_deivery	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Independent t test**
bishop score	Vaginal	85	4.5176	1.28741	.13964	2.202*
	LSCS	15	3.6667	1.83874	.47476	
Cervical Length	Vaginal	85	2.6376	.48794	.05292	5.374*
	LSCS	15	3.3667	.46240	.11939	





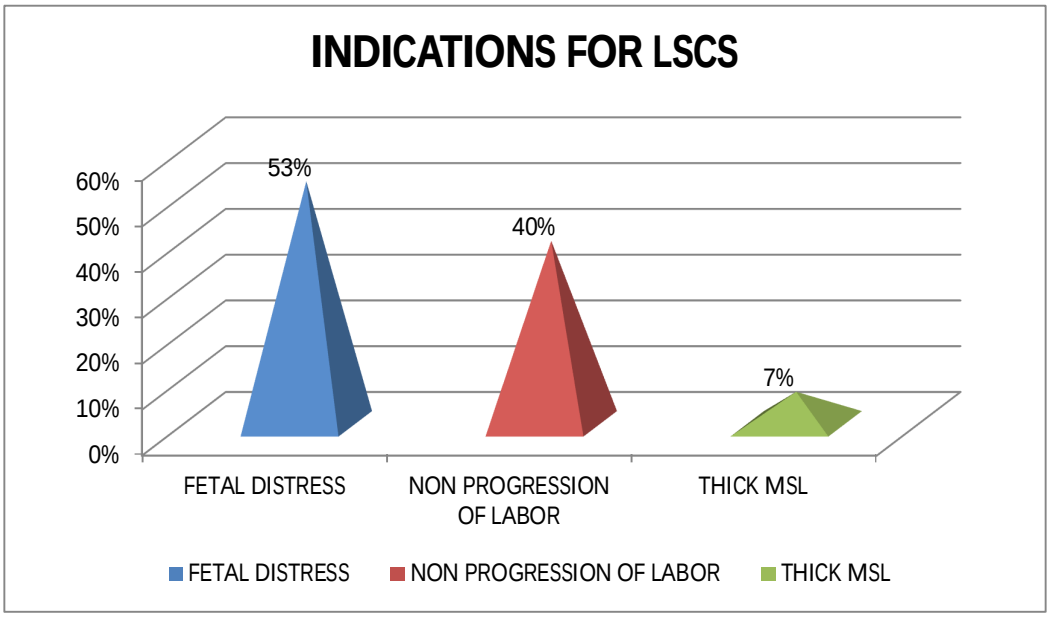
Crosstab					
			cv		Total
			<2.6	>2.6	
Age	15-20yrs	Count	14	19	33
		% within cv	27.5%	38.8%	33.0%
	21-25yrs	Count	28	21	49
		% within cv	54.9%	42.9%	49.0%
	26-30 yrs	Count	8	9	17
		% within cv	15.7%	18.4%	17.0%
	31-35 yrs	Count	1	0	1
		% within cv	2.0%	0.0%	1.0%
Total		Count	51	49	100
		% within cv	100.0%	100.0%	100.0%

Chi square 2.78 p>0.05 (0.427) non significant

TABLE 7 : INDICATIONS FOR LSCS

INDICATION	NUMBER (%)
FETAL DISTRESS	8 (53%)
NON PROGRESSION OF LABOR	6 (40%)
THICK MSL	1 (7%)
TOTAL	15

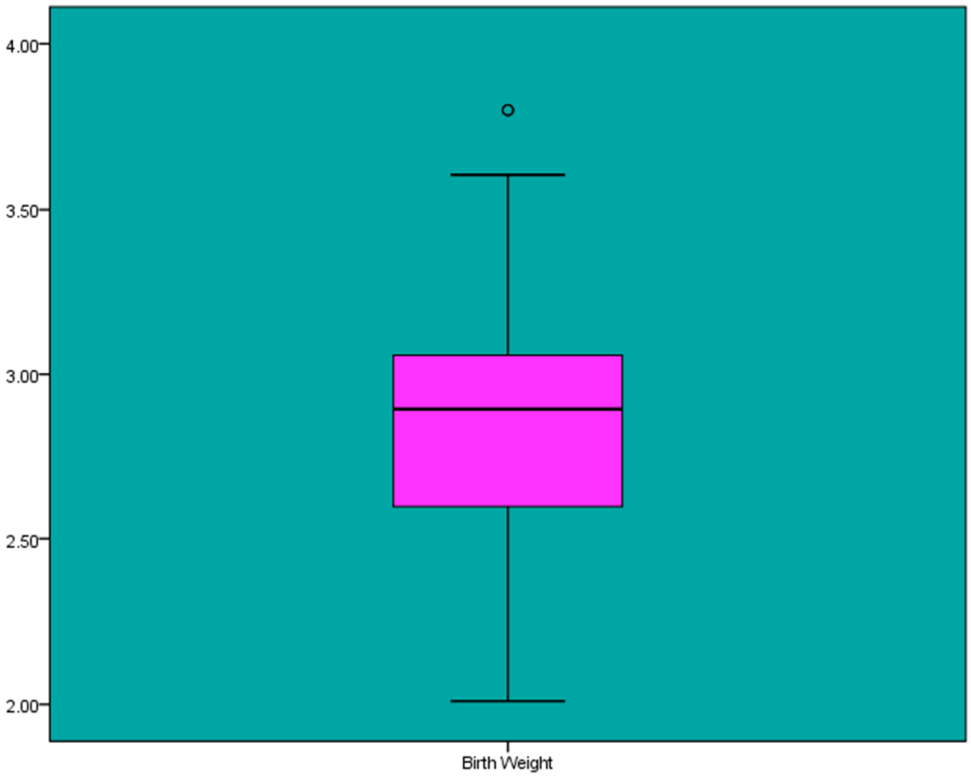
FIGURE 6 : INDICATIONS FOR LSCS



Out of 100 study patients 85 delivered vaginally, and 15 underwent LSCS. Out of 15 eight were for fetal distress and 6 were for non progression of labour (40%)

TABLE 8 : FETAL OUT COME

VARIABLE	MEAN±SD
BIRTH WEIGHT	2.87± 0.3629(2.01-3.8kg)
APGAR @ 5 MINUTE	8.90 ± 0.414 (6 – 9)
NICU Admission	**7 (7%)**



Descriptive Statistics					
	N	Minimum	Maximum	Mean	Std. Deviation
Apgar_Score_1_min	100	4.00	9.00	7.8700	.59722
Apgar_Score_5_min	100	6.00	9.00	8.9000	.41439
Valid N (listwise)					

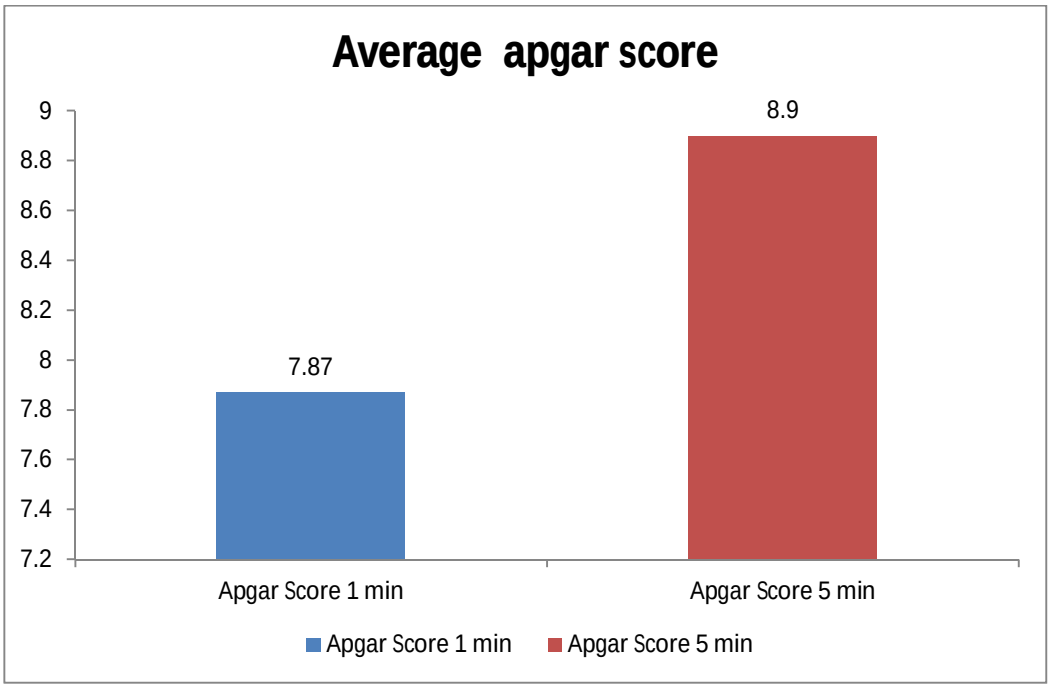
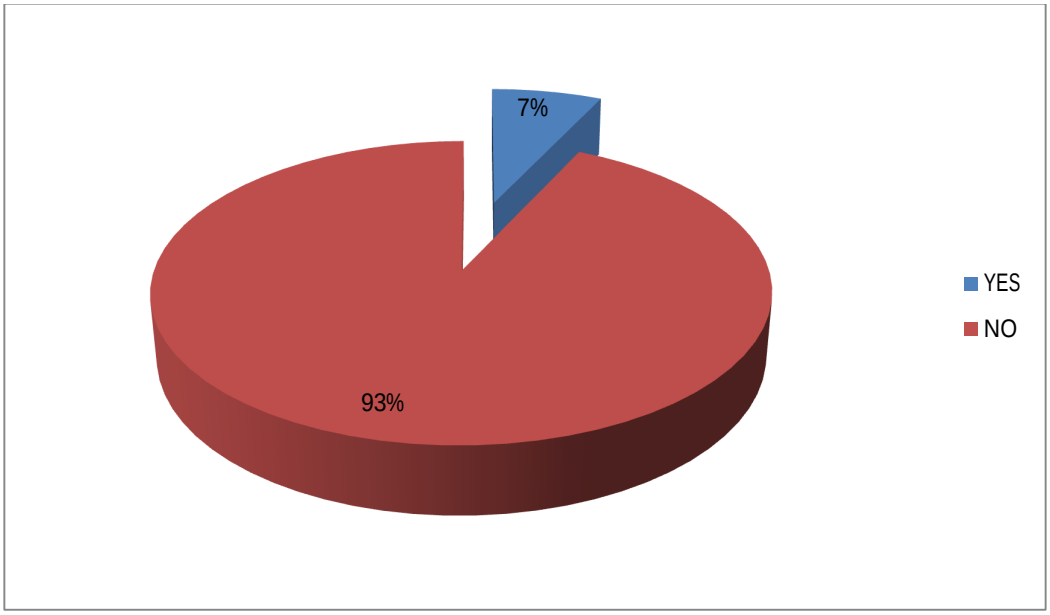


TABLE 9 : NICU ADMISSION

INDICATION	NUMBER (%)
YES	7 (7%)
NO	93 (93%)
TOTAL	100 (100%)



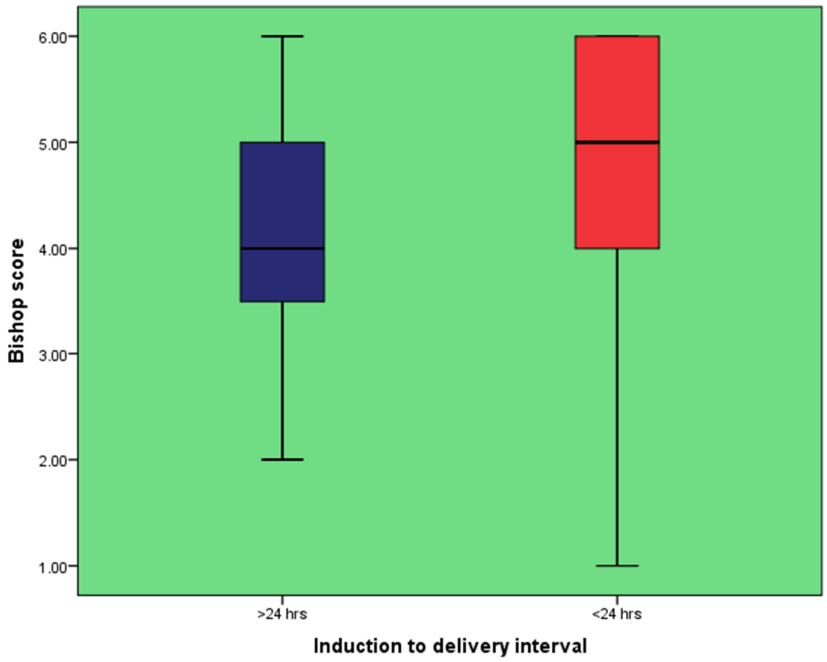
7% of neonates required NICU admission, 6 for respiratory distress and 1 with congenital malformation.

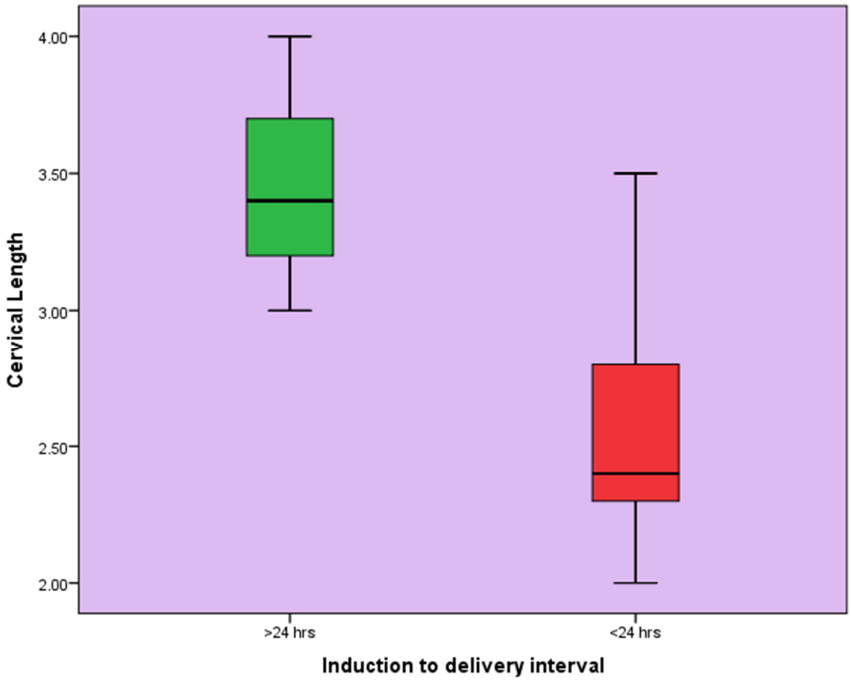
TABLE 10 : PRIMARY OUTCOME MEASURE

OUTCOME MEASURES	NUMBER (%)
Number of patients with Induction to Delivery interval < 24hrs	**74 (74%)**
Number of patients with Induction to active phase interval < 12hrs	**55 (55%)**

Group Statistics						
	Induction to delivery interval	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Independent t test**
bishop score	>= 24.00	11	4.1818	1.16775	.35209	0.926
	< 24.00	74	4.5676	1.30417	.15161	
Cervical Length	>= 24.00	11	3.4545	.31101	.09377	7.778*
	< 24.00	74	2.5162	.38107	.04430	

*p<0.001


6.00
5.00
4.00
3.00
2.00
1.00
Bishop score
>24 hrs
<24 hrs
Induction to delivery interval


4.00
3.50
3.00
2.50
2.00
Cervical Length
>24 hrs
<24 hrs
Induction to delivery interval

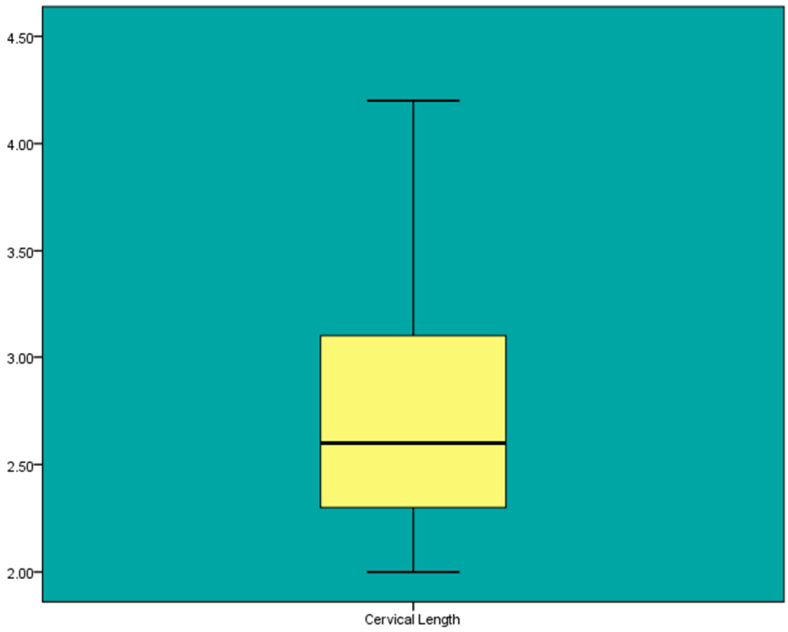
The above table depicts that bishop score was not significant differ for the woman whose delivery interval was within 24 hrs and more than 24 hrs. but cervical length shows there is significant difference in interval (within 24 />24 hrs).i.e if cervical length is more means period of delivery will be increased

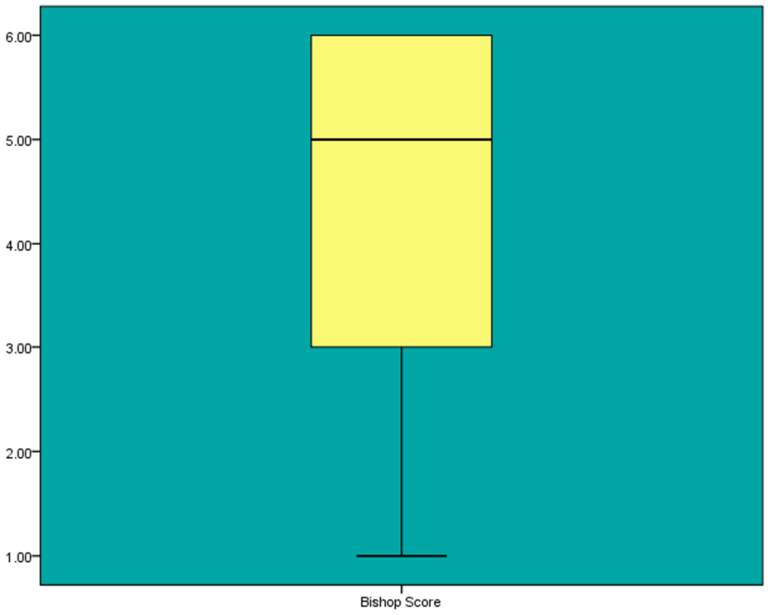
Crosstab					
			cv		**Total**
			<2.6	**>2.6**	
Age	15-20yrs	Count	14	19	33
		% within cv	27.5%	38.8%	33.0%
	21-25yrs	Count	28	21	49
		% within cv	54.9%	42.9%	49.0%
	26-30 yrs	Count	8	9	17
		% within cv	15.7%	18.4%	17.0%
	31-35 yrs	Count	1	0	1
		% within cv	2.0%	0.0%	1.0%
Total		Count	51	49	100
		% within cv	100.0%	100.0%	100.0%

The above table depicts that bishop score and cervical length was significant differ for the woman whose delivery interval was within 12 hrs and more than 12 hrs..i.e if cervical length is more means period of delivery will be increased similarly bishop score was increased means delivery period will increase.

TABLE 11

VARIABLE	MEAN ±SD
BISHOP SCORE	4.04± 0.99
CERVICAL LENGTH(TVS)	2.85± 0.46





CORRELATION OF THE OUTCOME MEASURES WITH MEAN BISHOP SCORE & CERVICAL LENGTH

TABLE 12

OUTCOME MEASURES	BISHOP SCORE	CERVICAL LENGTH In cms
Induction to delivery interval <24hrs(74)	4.1± 1	2.5± 0.4
Induction to active phase interval <12hrs (55)	4.6± 0.7	2.4± 0.3
Total number of vaginal deliveries	4.0±1	2.6±0.5

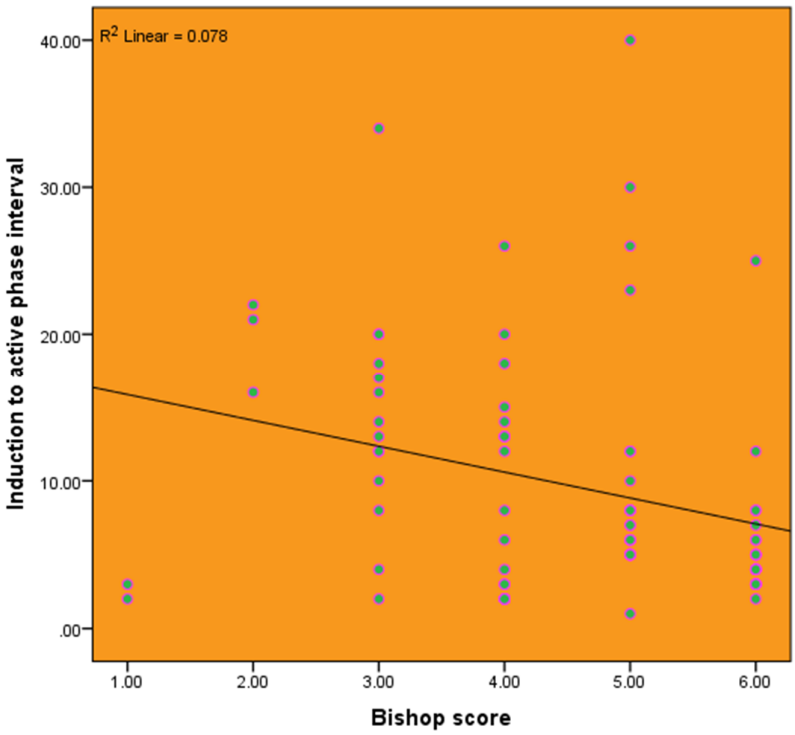
The mean Bishop score was 4.84 (1-6) and the distribution shown in figure 7

Descriptive Statistics				Induction to active phase interval	Induction to delivery interval
	Mean	Std. Deviation	N	Pearson Correlation r	Pearson Correlation r
bishop score	4.52	1.29	85	-.280**	-.274*
Cervical Length	2.64	.49	85	.875**	.886**

*. Correlation is significant at the 0.05 level

**. Correlation is significant at the 0.01 level

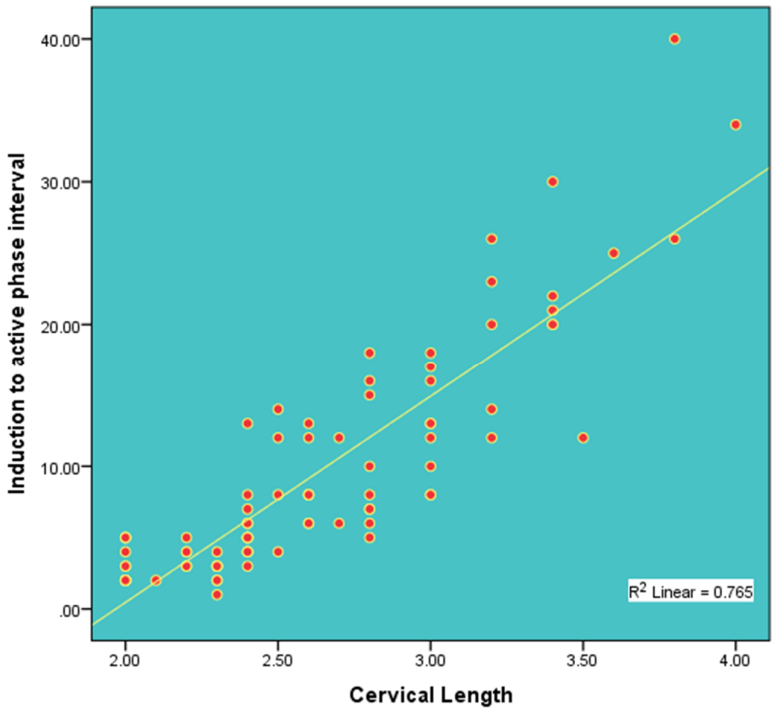
FIGURE 7



There was a significant negative correlation between the bishop score and the induction to delivery interval ($p<0.0001$). $R^2 = 0.078$ which means that only 7.8 % variation was explained by the bishop score for induction to active phase delivery.

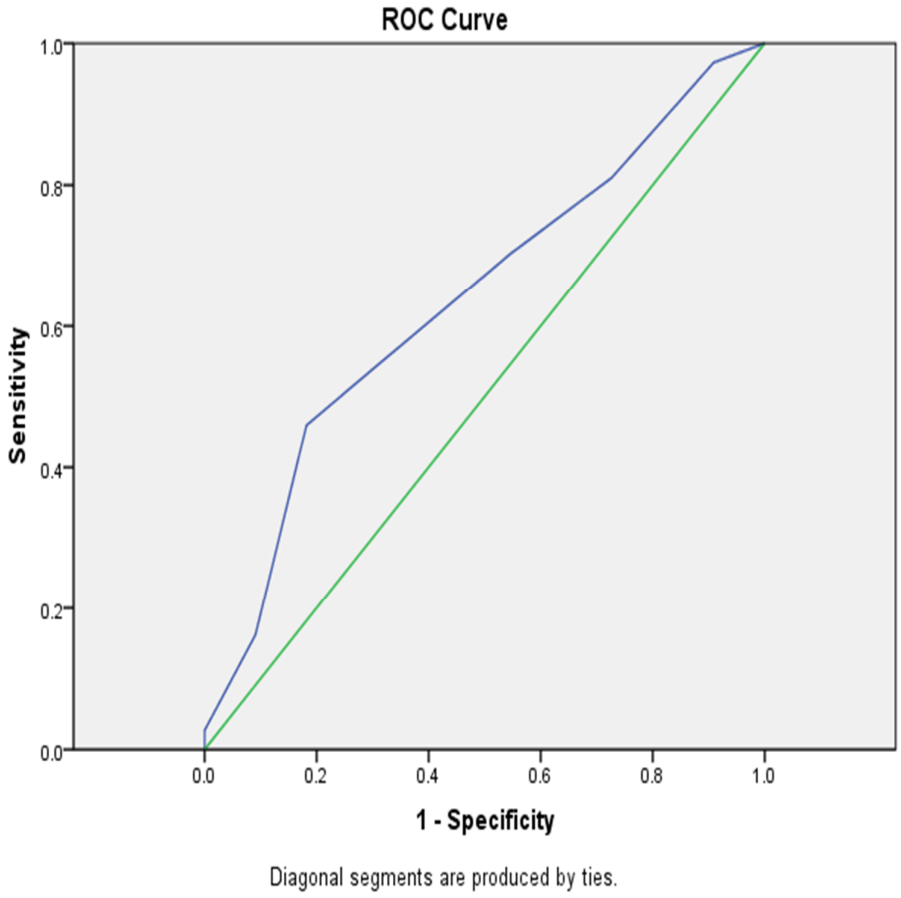
The mean Trans vaginal cervical length was 2.74cm, and the distribution is shown in figure 8

FIGURE 8



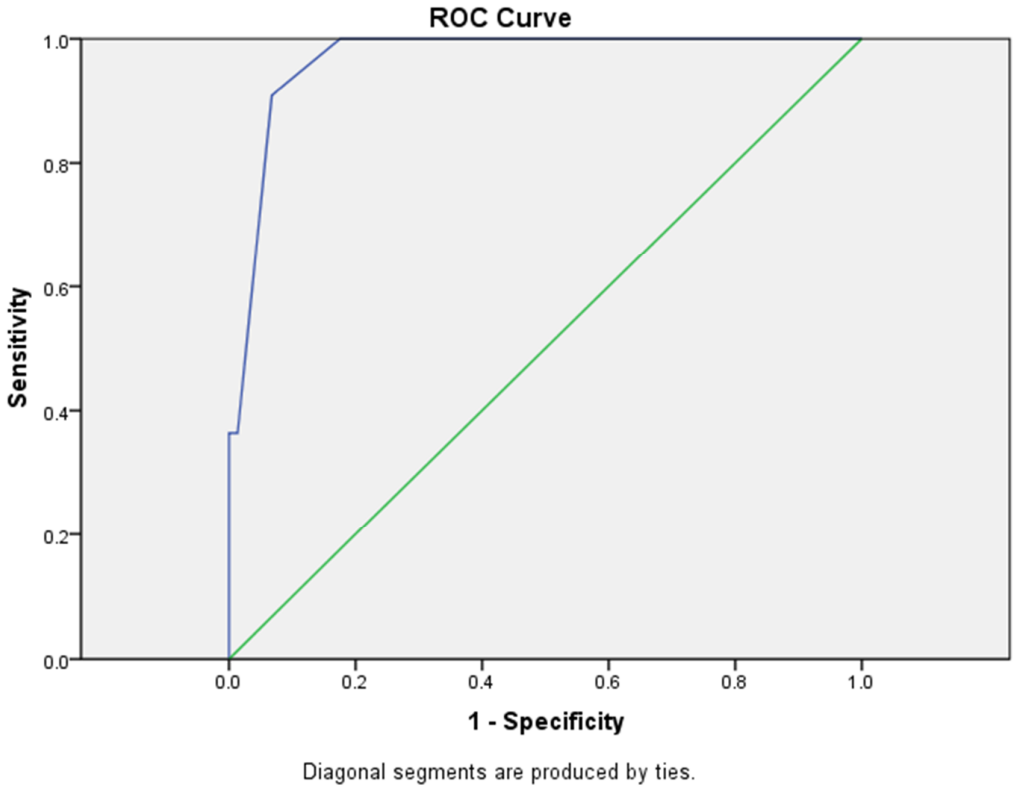
There was a significant positive correlation r =0.875 between cervical length and the Induction to delivery interval ($p<0.0001$). and R^2 = 0.765 which means that 75.5 % variation was explained by the cervical length

Receiver – operating characteristic curves for the correlation of bishop score and Induction to delivery interval <24 hrs



Area under the curve is 0.638*

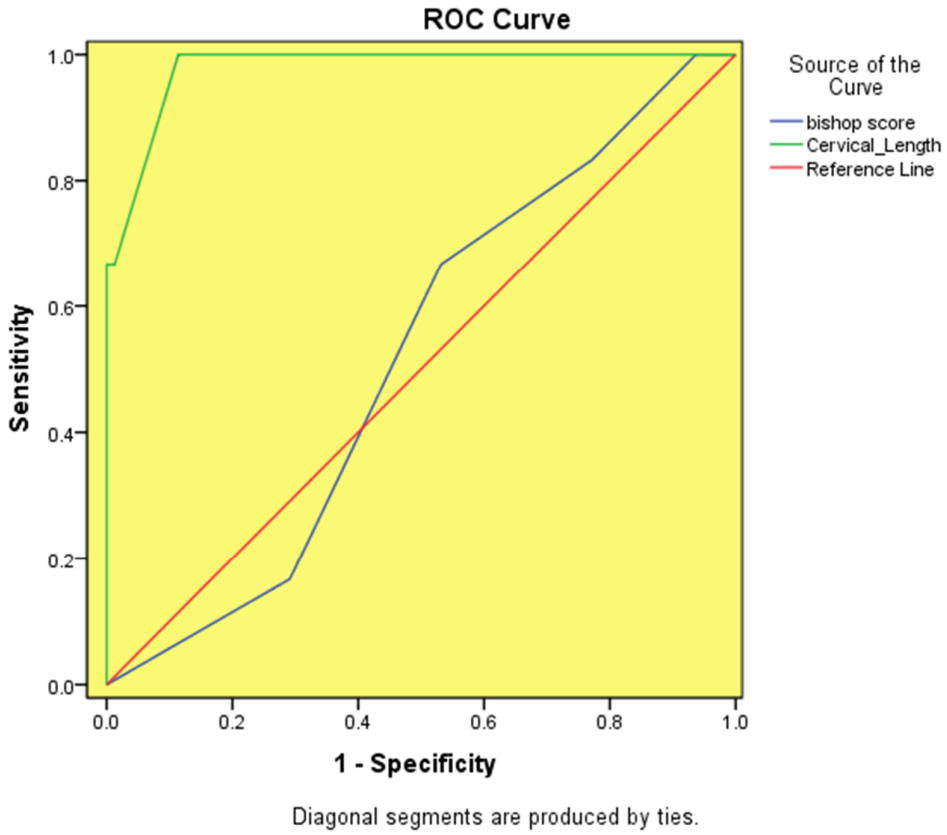
Receiver – operating characteristic curves for the correlation of transvaginal cervical length and induction to delivery interval



The area under the curve is 0.967* ($p<0.05$)

However, cervical length appears to be a better predictor than the Bishop Score with a sensitivity of 0.703 and a specificity of 0.82 compared to 0.9 and 0.94 respectively

In the receiver operating characteristic curves, the best cut-off point for the prediction of successful induction was 2.6cm cervical length and 4 for the bishop score.



Bishop score around 4 and transvaginal cervical length around 2.6 are found to be best cut-off values for the pre induction cervical condition. Taking Bishop Score 4 and Cervical length 2.6 as the cut off and taking successful induction of labour as delivery within 24hrs.The predictive values were compared and shown in Table 13.

TABLE 13

VARIABLE	SENSITIVITY	SPECIFICITY	PPV	NPV	PREDICTIVE VALUE
BISHOP SCORE ≥4	70.3%	45.5%	89.7%	18.5%	0.296
TVS CERVICAL LENGTH ≤2.6	58.1%	100%	100%	26.2%	<0.001

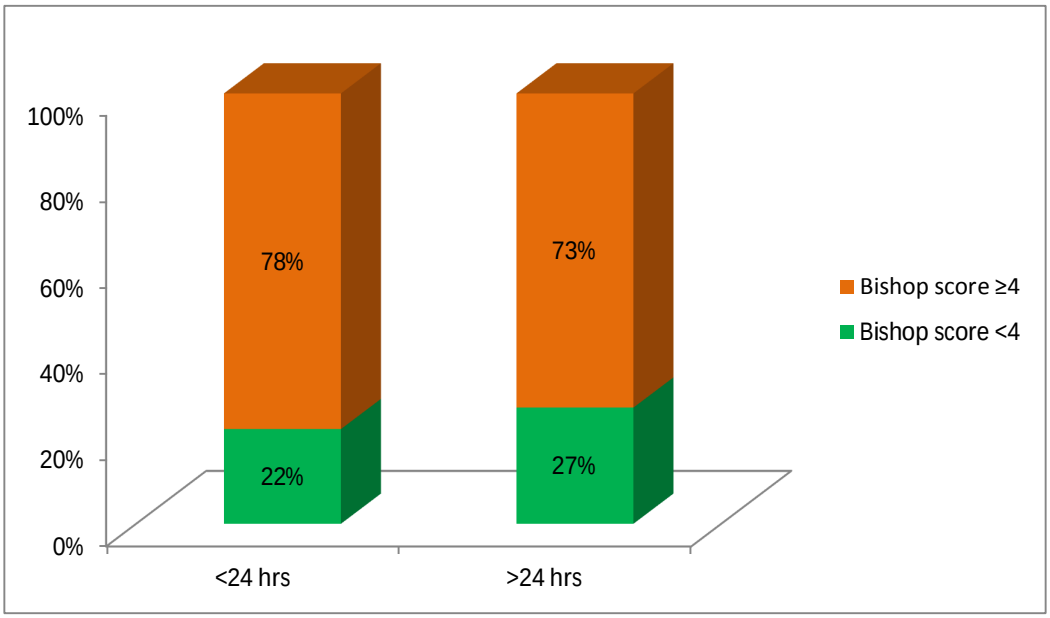
Though Bishop score has more sensitivity than cervical length, specificity and positive predictive value of the trans vaginal cervical length is 100%. Significant predictive value is obtained for cervical length <0.001. P value for Bishop Score is 0.296. So trans vaginal cervical length found to be better predictor of successful induction of labour in terms of delivery within 24hrs when compared to Bishop Score.

TABLE 14

COMPARISON OF NUBER OF WOMEN UNDELIVERED AT 24hrs

Induction to delivery interval<24 *bishop score Crosstabulation					
			bishop score		Total
			<4	≥4	
Induction to delivery interval <24	<24 hrs	Count	16	58	74
		% within bishop score	22%	78%	100%
	>24 hrs	Count	3	8	11
		% within bishop score	27%	73%	100%
Total		Count	19	66	85
		% within bishop score	22%	78%	100.0%

Chi square = 0.176 p= 0.675 non significant



Crosstab delivery interval and cervical length					
			cv		Total
			≤2.6	>2.6	
Day	<24 hrs	Count	50	24	74
		% within day	67.6%	32.4%	100.0%
	>24 hrs	Count	0	11	11
		% within day	0.0%	100.0%	100.0%
Total		Count	50	35	85
		% within day	58.8%	41.2%	100.0%

Chi square = 18.05*p<0.01 significant

TABLE 15 : COMPARISON OF NUMBER OF WOMEN UNDELIVERED AT 24hrs

VARIABLE	NO. OF DELIVERIES WITHIN 24hrs	NO. UNDELIVERED AT 24hrs	TOTAL
BISHOP SCORE ≥4	68 (90%)	6 (10%)	74
TVS Length ≤2.6	74 (100%)	0 (0%)	74

Further comparing the prediction of women who remained undelivered at 24hrs, we found that 10% of women with Bishop Score ≥4 remained undelivered when compared to none with a TVS cervical length of ≤2.6cm

This points towards TVS cervical length being a better predictive of successful labour induction compared to Bishop Score.

Discussion

DISCUSSION

This study has demonstrated that, in primi singleton pregnancies undergoing induction of labor with dinoprostone gel at 37-42 wks, successful vaginal delivery within24hrs of induction occured in approximately 74%. The study has also demonstrated that induction to delivery interval is significantly associated with both the preinduction bishop score and the sonographically measured cervical length, higher the Bishop score and lesser the cervical length better the likelihood of vaginal delivery. TVS cervical length was a better predictor of successful labour induction in terms of delivery within 24hrs of induction.

Previous studies on the value of pre-induction sonographic measurement of cervical length have reported conflicting results. Paterson Brown et al[98]. examined 50 pregnancies before induction and reported that, although the Bishop Score correlated significantly with successful vaginal delivery, the score fell well short of being a satisfactory predictor of successful induction. In addition they found that sonographically measured cervical length was not significantly associated with either the Bishop Score or the induction to delivery interval. Boozarjomehri et al[99]. Examined 53 women before induction and reported that, although sonographically measured cervical length was correlated with the duration of the latent phase of the labour , there was no significant association with the induction to delivery interval or to cervical effacement measured by digital examination.

Watson et al [100]. Examined 109 women before induction and reported a significant association between sonographically measured cervical length and clinical assessment of cervical effacement; however, neither of the two provided a useful prediction of the length of the latent phase of labour. Gonen et al [101] examined 86 women before induction and reported significant association between both the Bishop Score and sonographically measured cervical length with successful induction and induction to delivery interval. Ware and Raynor[102] examined 77women before induction and found that both sonographically measured cervical length and Bishop score predicted induction-to-delivery interval and likelihood of vaginal delivery. In a logistic regression model, only cervical length and parity were independent predictors of vaginal delivery.

Pandis et al [103]. Conducted a study on 240 women with singleton pregnancies at 37-42wks of gestation Vaginal delivery occurred in 194(80.8%) women and in 142(73.2%) of these delivered within 24hrs of induction. In our study 85% delivered vaginally and 74% delivered within 24hrs. Table 15 shows the comparison of the primary outcome measures in our study with the other study.

COMPARISON OF THE PRIMARY OUTCOME MEASURES WITH OTHER STUDY

OUTCOME MEASURES	PANDIS ET AL (Total No.240) No. (%)	THIS STUDY (Total No. 100) No. (%)
Number of vaginal delivery	194 (80.4%)	85 (85%)
Number of LSCS	46 (19.2%)	15 (15%)
Number delivered within 24hrs	142 (73.2%)	74 (74%)

In our study we defined successful induction of labour as vaginal delivery occurring within 24 hrs. This end point has been traditionally used in several studies to examine the efficacy of an inducing method. P Rozenberg et al[104] compared the Bishop score and sonographically assessed cervical length for the prediction of successful induction as delivery within 24 hrs of induction. Pandis et al. also demonstrated that cervical length by ultrasound performed better than Bishop Score to predict vaginal delivery wihin 24hrs of induction.

Both sonographic cervical assessment and the Bishop Score successfully predicted vaginal delivery within 24 hrs. As the cervical length increases the likelihood of delivering within 24hrs decreases whilst, as bishop score increase, the likelihood of delivering within 24hrs increases. However, the receiver operating characteristic curves for the two variables showed that, the sensitivity of sonologically measured cervical length in predicting successful induction of labour was higher than that for the Bishop Score.ROC curves were constructed to determine appropriate cut off for bishop score and

trans vaginal cervical length in predicting the labour induction, shown 4 is the best cut off for Bishop Score and 2.6 is for trans vaginal cervical length.

Sujata et al[105]. Conducted study on 122 patients and their ROC curves failed to identify an appropriate cut off for continuous variables relating to sonographic cervical measurements. These variables were, therefore, analyzed as continuous variables in the regression model . Independent predictors of vaginal delivery included Bishop Score, cervical position, and maternal age. In their study trans vaginal ultrasound does not predict successful labour induction as well as digital cervical examination.

In our study though the sensitivity of the Bishop Score in predicting the successful labour induction is higher (70.3%) compared with that of cervical length measured trans vaginally (58.1%) the specificity and positive predictive value for the cervical length was 100% compared with the Bishop Score (45.5% and 89.7% are respectively)

Two larger studies have been published, which compared Bishop Score and transvaginal ultrasound in preinduction cervical assessment. In a study of 109 women,Watson et al[100]. Used regression modelling to determine factors associated with successful induction. They determined that only cervical dilatation, as assessed by clinical examination, was a predictor of induction success. Likewise, Gonen et al[101]. prospectively evaluated 86 study subjects and found that only Bishop Score and parity were independent predictors of vaginal delivery in induced labour.

Interestingly, a recent randomised study comparing use of transvaginl sonographic assessment and Bihop Score to guide preinduction cervical ripening with prostaglandins has shown a reduction in prostaglandin use without affecting successful labour induction with trans vaginal ultrasonography.

The survival analysis demonstrated better discriminatory results in favour of cervical length without any women in short cervix (0-1.8cm)remaining undelivered after 24hrs compared to 10% of women in the high Bishop Score group (5-8). 67% of the long cervix group (3.2-5cm) remained undelivered after 24 hrs compared to 33% of women in the low Bishop Score group. These findings suggest that sonographic cervical length is a better test than the Bishop Score for predicting successful induction of labour

But the limitations for obtain TVS cervical length are that the expensive equipment and also the technical expertise in measuring the cervical length in standard and reproducible manner is required, so as to avoid the errors in the measurement. It is also an expensive test.

In the setting where Transvaginal sonographic measurement of cervical length can be achieved easily, correctly and with minimal discomfort to the patient, it provides a useful prediction of the likelihood of vaginal delivery within 24 hrs of induction and of the induction to delivery interval. It helps in counseling the women regarding the outcome of labour induction.

Women with a cervical length of less than 2.6 cm can be counseled that delivery will possibly occur within 24 hrs of induction , whereas those with cervical length of 3cm can be advised that they have an approximately 67% chance of remaining undelivered after this interval.

Bishop score still remains a useful test in the setting where the equipment and experts are not available as it is a simple, inexpensive test and does not required technical expert.

LIMITATIONS OF THE STUDY

1. Did not analysis the different components of bishop score separately to see which factor can contribute to the successful prediction in induced labour.

2. Did not include the other parameters of the transvaginal cervical assessment like dilation, presence of wedging, or cervical angle which could have probably added in the predictability obtained by cervical length alone.

3. Association of other factors like maternal weight, maternal age, are not considered in our study. It can be independent predictors in successful labour induction.

Conclusion

CONCLUSION

Bishop score and transvaginal cervical length both are good predictors of successful induction of labour. **Transvaginal cervical length provides a better prediction of the likelihood of vaginal delivery within 24hrs of induction.** TVS cervical length could be used as a better alternative to Bishop Score for successful labour induction in the setting where the appropriate equipment and expertise are available.

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Annexures

PROFORMA

NAME : AGE: OP/IP No:

OCCUPATION:

LMP: EDD: GA at intervention

Indication for induction of labour :

Medical Complications :

Gestational Age: Expected Fetal Weight :

Trans vaginal cervical length :

Obstetric Complications:

USG Findings:

Amniotic Fluid Index:

BISHOP SCORE

Dilatation	Effacement	Station	Cervical consistency	Cervical position

TOTAL SCORE

Induction to active phase interval :

Induction to delivery interval :

Mode of delivery :

A) Vaginal :

B) Vaginal instrumental :

C) LSCS :

Indication for LSCS :

Indication for instrumental delivery :

Fetal outcome

a) Birth weight :

b) Apgar score :

1 minute :

5 minute :

Neonatal ICU Admission :

Indication for ICU Admission :

KEY TO MASTER CHART

AGE

1=15-20yrs

2=21-25yrs

3=26-30yrs

4=31-35yrs

5=36-40yrs

OCCUPATION

1-Professional

2-House wife

INDICATION FOR INDUCTION OF LABOUR

1-Post datism

2-Mild PIH

3-Prolonged latent Phase

4-Decreased AFI

5-Decreased fetal movements

DILATATION

0= Closed

1=1-2cm

2=3-4cm

3=≥5cm

EFFACEMENT

0=3cm

1=2cm

2=3cm

3=0cm

STATION

0= -3

1= -2

2= -1

3=+1,+2

CERVICAL CONSISTANCY

0-firm

1-medium

2-soft

CERVICAL POSITION

0-posterior

1-mid position

2-anterior

MODE OF DELIVERY

1-Vaginal

2-Vaginal Instrumental

3-LSCS

NICU ADMISSION

1-yes

2-No

INDICATION FOR NICU ADMISSION

1-Respiratory distress

2-Grunting

3-Cyanosed

4-Malformation

1	2	3	4	5	6	7	8

S. No.	Age	Occupation	GA (In days)	Indication for induction	Complications	USG Findings				Bishopscore			
						GA (in days)	EFW (in kgs)	AFI (in CM)	Cervical Length (IN cm)	Dilatation	Effacement	Station	Cervical Consistency
1.	2	2	281	1	decreased AFI (6.5)	266	3.14	6.5	3.4	1	0	0	2
2.	2	2	276	1	nil	242	2.6	13	2.3	0	0	1	2
3.	2	2	280	1	nil	266	3	9	2.8	1	0	0	2
4.	1	2	274	1	nil	266	2.6	12	2.7	1	0	1	2
5.	2	2	281	1	nil	252	2.6	7	2.3	1	1	1	2
6.	2	2	280	1	nil	273	2.7	11.5	2.4	1	0	0	2
7.	2	2	278	3	nil	273	3	16	3.4	1	1	0	0
8.	3	2	278	2	nil	261	2.9	10	3.6	0	0	0	2
9.	2	1	281	2	Rh-ve,hypothyroidism	259	2.4	12	3.4	1	1	1	2
10.	1	2	280	1	anemia	266	2.8	6	3.2	1	0	0	2
11.	2	2	278	1	nil	273	3	16	3.4	1	1	0	2
12.	2	2	285	1	nil	280	3.2	12	2	0	0	0	2
13.	3	1	280	1	AFI(7)	259	2.6	7	3.2	1	0	1	2
14.	1	2	276	1	nil	252	2.8	8.2	2.4	1	1	1	2
15.	1	2	260	1	nil	259	2.8	7.2	2.8	1	1	0	2
16.	1	2	282	3	nil	256	3.088	8	2.7	1	1	1	2
17.	1	2	273	3	mild PIH	259	2.7	12	3.6	1	0	1	2
18.	2	2	280	1	nil	280	3	10.2	3.8	1	0	1	2
19.	2	2	263	1	nil	259	2.8	12	2	1	1	2	2
20.	1	2	274	2	nil	266	2.7	12	2	1	1	2	2
21.	2	2	278	2	nil	248	2.5	8	2.6	1	1	1	2
22.	1	2	282	2	nil	271	3.2	9	3	1	1	1	2
23.	2	2	282	2	Rh-ve	259	3	10.5	2	1	2	1	2
24.	1	2	260	3	nil	245	2.4	9.3	3.2	1	1	0	2
25.	3	2	271	1	nil	245	2.4	9	2	1	1	1	2
26.	3	2	277	1	nil	280	3.2	7	4	0	0	0	2

S. No.	Age	Occupation	GA (In days)	Indication for induction	Complications	USG Findings				Bishopscore			
						GA (in days)	EFW (in kgs)	AFI (in CM)	Cervical Length (IN cm)	Dilatation	Effacement	Station	Cervical Consistency
27.	1	2	279	1	nil	268	2.88	11	2.8	0	0	1	2
28.	2	2	281	1	nil	280	2.6	10	2.8	1	0	1	2
29.	2	2	280	1	mild PIH	273	2.5	10	2.4	0	0	1	2
30.	1	2	261	4	nil	266	2.8	12	2	1	1	1	2
31.	2	2	268	1	nil	252	2.9	8.3	2.4	1	1	0	2
32.	1	2	269	1	nil	243	2.5	10	2.8	1	0	0	2
33.	2	2	253	1	nil	252	2.7	7	3.4	0	0	1	2
34.	2	2	261	1	impaired GTT	252	2.4	16	2.2	1	1	1	2
35.	2	2	263	1	nil	256	2.9	7	3.2	1	0	1	2
36.	2	2	264	2	nil	256	2.9	10.5	2.3	2	1	1	2
37.	2	2	269	2	nil	255	2.7	12.5	2.5	1	0	1	2
38.	1	2	271	2	nil	266	2.6	10.5	2.8	1	1	0	2
39.	2	2	277	3	nil	266	2.4	12.5	3	1	0	0	2
40.	3	2	258	3	nil	238	2.1	7	3	1	0	0	0
41.	2	2	267	1	hypothyroidism	255	2.6	12	2.5	1	0	0	2
42.	2	2	284	1	PTB	259	2.9	10	2.6	1	1	0	2
43.	1	2	277	1	anemia	266	2.8	10	2.2	1	1	0	2
44.	3	2	271	2	nil	259	3.096	10	2.4	1	0	0	2
45.	1	2	281	2	nil	245	2.5	8.2	3.5	1	0	1	2
46.	2	2	281	3	nil	273	2.6	12.5	2	0	0	1	2
47.	2	2	278	2	nil	259	2.7	10	2.5	1	1	1	2
48.	3	2	280	1	nil	269	3.5	10	3.6	0	0	1	2
49.	2	2	250	1	nil	240	2.4	7	2.2	1	1	1	2
50.	1	2	270	2	hyperthyroidism	259	2.7	10.5	2.4	1	1	1	2
51.	3	2	263	1	nil	245	2.2	10	2.4	1	1	0	2
52.	1	2	279	2	nil	273	2.8	7	2.4	1	1	1	2
53.	2	2	278	1	anemia	273	2.9	10	2.6	1	1	1	2
54.	3	2	273	2	hypothyroidism	266	2.8	8	2.8	1	0	0	2
55.	3	2	276	1	nil	276	2.8	9	2.3	0	0	1	2

S. No.	Age	Occupation	GA (In days)	Indication for induction	Complications	USG Findings				Bishopscore			
						GA (in days)	EFW (in kgs)	AFI (in CM)	Cervical Length (IN cm)	Dilatation	Effacement	Station	Cervical Consistency
56.	1	2	259	5	nil	259	2.8	7.3	2	0	0	1	2
57.	2	2	278	2	nil	266	2.7	15	2.8	1	1	1	2
58.	1	2	267	1	nil	273	2.5	12	3	1	1	1	2
59.	1	2	278	1	nil	273	2.7	8.5	3.2	1	0	0	2
60.	4	2	269	1	nil	266	2.6	9.6	2.6	1	0	1	2
61.	1	2	287	1	nil	259	2.8	10	3	1	0	2	0
62.	1	2	270	1	nil	252	2.3	12	3.6	0	0	0	2
63.	2	2	277	1	nil	238	2	8	2.8	1	1	0	2
64.	1	2	262	1	nil	252	2.4	11	2.6	1	1	1	2
65.	2	2	277	3	nil	273	3.5	13	3.6	0	0	0	2
66.	1	2	264	1	nil	252	2.6	8	2	1	1	1	0
67.	3	2	290	2	nil	277	3.2	6	2.4	1	1	1	2
68.	2	2	275	2	abnormal OGCT	273	2.7	12	2.4	1	1	1	2
69.	2	2	276	2	nil	262	3.2	10	3	1	1	0	2
70.	2	2	276	2	nil	266	3	10.4	2.2	1	2	0	2
71.	1	2	281	2	nil	273	2.8	9	3.2	1	0	0	2
72.	3	2	271	1	nil	266	3	12	2	0	0	1	2
73.	2	2	268	1	nil	273	3.3	11	3	0	0	1	2
74.	2	2	264	1	nil	238	2.16	10	2.1	0	0	1	2
75.	3	2	281	3	nil	273	2.7	11	4.2	1	0	0	2
76.	1	2	283	3	nil	266	2.5	13	3.8	1	0	1	2
77.	2	2	266	3	nil	259	2.4	12	2.3	1	1	1	2
78.	2	2	273	3	nil	266	3.1	11	2	1	1	1	2
79.	3	2	283	4	nil	273	3.1	20	3.4	0	0	0	2
80.	1	2	252	2	nil	248	2.58	9	2.4	1	1	1	2
81.	3	2	275	2	nil	266	2.5	10	2.3	1	1	1	2
82.	1	2	273	2	nil	259	2.4	12	2.6	1	1	1	2
83.	1	2	266	1	Rh negative	259	3	8	2	0	0	0	0
84.	2	2	279	1	nil	266	3.4	14	3	1	1	1	2

S. No.	Age	Occupation	GA (In days)	Indication for induction	Complications	USG Findings				Bishopscore			
						GA (in days)	EFW (in kgs)	AFI (in CM)	Cervical Length (IN cm)	Dilatation	Effacement	Station	Cervical Consistency
85.	2	2	281	1	nil	273	3	11	3.8	0	0	1	0
86.	3	2	267	3	nil	266	2.5	8	2.4	1	1	1	2
87.	3	2	285	2	nil	287	3	8	3.8	0	0	0	0
88.	1	2	281	1	nil	283	2.8	16.5	2.2	1	1	1	2
89.	2	2	266	1	nil	259	2.4	12	2.6	1	1	1	2
90.	1	2	270	1	nil	259	2.7	8	2.8	1	0	1	2
91.	2	2	266	1	nil	259	2.7	10	3	1	0	1	0
92.	2	2	272	2	nil	259	2.9	8	2.5	1	0	0	2
93.	2	2	264	1	nil	252	2.6	16	3	1	0	1	2
94.	2	2	281	1	nil	273	2.5	9	3.5	0	0	0	2
95.	2	2	266	1	nil	259	2.7	10	2.4	1	1	1	2
96.	2	2	278	1	nil	266	3.5	10	3	1	1	1	2
97.	2	2	271	2	nil	266	3	10	2.4	0	0	0	0
98.	1	2	276	2	nil	276	2.8	9	2.3	0	0	1	2
99.	1	2	266	2	nil	273	3.3	11	3	0	0	1	2
100.	2	2	266	2	nil	259	2.4	12	2.3	1	1	1	2

9	10	11	12	13	14	15	16	17

S. No.	Cervical position	Total	Induction to active phase interval	Induction to delivery interval	Mode of Delivery	Indication for LSCS	Fetal Outcome			NICU Admission	Indication for ICU Admission
							Birth Weight	Apgar Score			
								1 min	5 min		
1.	0	3	20	23	1		3.4	4	6	1	1
2.	1	4	2	3	1		2.51	8	9	2	
3.	1	5	5	8	1		3.25	8	9	1	2
4.	1	5	6	8	1		2.39	8	9	1	2
5.	0	5	1	4	1		2.74	7	9	1	3
6.	0	3	13	15	1		2.71	8	9	2	
7.	0	2	21	23	1		3.235	7	9	2	
8.	0	2	25		3	fetal distress	3.055	8	9	2	
9.	0	5	48		3	NPL	2.68	8	9	2	
10.	0	3	14	17	1		2.83	8	9	2	
11.	1	5	30	33	1		3.235	7	8	2	
12.	2	4	3	5	1		3.43	8	9	2	
13.	0	4	12	15	1		2.97	8	9	2	
14.	1	6	5	8	1		2.66	8	9	2	
15.	0	4	15	18	1		3.05	8	9	2	
16.	0	5	12	14	1		3.03	7	9	2	
17.	1	6	25	28	1		2.37	8	9	2	
18.	1	5	40	45	1		3.12	8	9	2	
19.	2	6	5	7	1		2.97	8	9	2	
20.	0	6	5	8	1		2.855	8	9	2	
21.	1	6	12	14	1		2.62	8	9	2	
22.	0	5	8	13	1		3.1	8	9	1	2
23.	0	6	4	10	1		2.89	8	9	2	
24.	1	5	23	26	1		2.77	8	9	2	
25.	0	5	5	8	1		2.01	8	9	2	
26.	1	3	34	38	1		3.48	8	9	2	

S. No.	Cervical position	Total	Induction to active phase interval	Induction to delivery interval	Mode of Delivery	Indication for LSCS	Fetal Outcome			NICU Admission	Indication for ICU Admission
							Birth Weight	Apgar Score			
								1 min	5 min		
27.	0	3	10	15	1		2.93	8	9	2	
28.	1	5	12		3	fetal distress	2.95	8	9	2	
29.	0	3	8	14	1		2.82	8	9	2	
30.	1	6	3	5	1		2.98	8	9	2	
31.	1	5	5	7	1		2.805	8	9	2	
32.	0	3	18	22	1		2.65	8	9	2	
33.	0	3	20	26	1		2.91	8	9	2	
34.	1	6	3	6	1		2.45	8	9	2	
35.	1	5	24		3	NPL	3.055	8	9	2	
36.	0	6	3	5	1		2.56	8	9	2	
37.	0	4	14	16	1		3.455	8	9	2	
38.	0	4	6	8	1		3.02	8	9	2	
39.	1	4	13	15	1		2.72	8	9	2	
40.	1	2	16	20	1		2.2	8	9	2	
41.	0	3	12	14	1		2.9	8	9	2	
42.	0	4	13	16	1		3.115	8	9	2	
43.	1	5	5	7	1		2.865	8	9	2	
44.	0	3	4	6	1		2.73	8	9	2	
45.	1	5	12	20	1		2.8	8	9	2	
46.	1	4	2	4	1		3.06	8	9	2	
47.	1	6	4	7	1		2.3	8	9	2	
48.	0	3	28		3	NPL	3.115	8	9	2	
49.	1	6	4	5	1		2.36	8	9	2	
50.	0	5	6	8	1		3.05	8	9	2	
51.	0	4	4	8	1		2.6	8	9	2	
52.	1	6	5	8	1		2.5	8	9	2	
53.	1	6	6	8	1		2.94	8	9	2	
54.	0	3	16	18	1		2.23	8	9	2	
55.	1	4	3	5	1		2.55	8	9	2	
56.	1	4	2	4	1		2.9	7	8	2	

S. No.	Cervical position	Total	Induction to active phase interval	Induction to delivery interval	Mode of Delivery	Indication for LSCS	Fetal Outcome			NICU Admission	Indication for ICU Admission
							Birth Weight	Apgar Score			
								1 min	5 min		
57.	0	5	7	9	1		3.06	8	9	2	
58.	0	5	10	12	1		2.66	8	9	2	
59.	1	4	20	24	1		2.82	8	9	2	
60.	1	5	8	10	1		3.08	8	9	2	
61.	0	3	17	22	1		2.64	8	9	2	
62.	1	3	29		3	fetal distress	2.5	8	9	2	
63.	1	5	7	10	1		2.5	8	9	2	
64.	1	6	6	10	1		2.97	8	9	2	
65.	0	2	23		3	thick MSL	3.01	7	8	1	2
66.	0	3	2	3	1		2.54	8	9	2	
67.	1	6	4		3	fetal distress	2.44	8	9	2	
68.	1	6	4	6	1		3.33	8	9	1	4
69.	1	5	10		3	fetal distress	3	8	9	2	
70.	1	6	4	8	1		3.38	9	9	2	
71.	1	4	26	28	1		3.42	8	9	2	
72.	1	4	2	4	1		3.085	9	9	2	
73.	1	4	18	24	1		3.8	8	9	2	
74.	1	4	2	3	1		2.4	6	7	2	
75.	0	3	40		3	NPL	2.93	8	9	2	
76.	1	5	26	30	1		2.84	8	9	2	
77.	1	6	3	6	1		2.57	8	9	2	
78.	1	6	2	4	1		3.19	8	9	2	
79.	0	2	22	27	1		2.88	8	9	2	
80.	0	5	5	9	1		2.353	8	9	2	
81.	1	6	4	8	1		2.4	8	9	2	
82.	1	6	8	12	1		2.1	8	9	2	
83.	1	1	2	4	1		3.037	8	9	2	
84.	1	6	10		3	fetal disterss	3.58	8	8	2	
85.	0	1	32		3	fetal distress	3.605	8	9	2	
86.	0	5	6	10	1		2.515	8	9	2	

S. No.	Cervical position	Total	Induction to active phase interval	Induction to delivery interval	Mode of Delivery	Indication for LSCS	Fetal Outcome			NICU Admission	Indication for ICU Admission
							Birth Weight	Apgar Score			
								1 min	5 min		
87.	1	1	30		3	fetal distress	3.3	6	8	2	
88.	1	6	3	8	1		2.9	6	9	2	
89.	0	5	8	10	1		2.6	8	9	2	
90.	1	5	8	12	1		2.85	8	9	2	
91.	1	3	12	16	1		2.81	8	9	2	
92.	0	4	8	12	1		3	9	9	2	
93.	2	6	8	12	1		3	8	9	2	
94.	0	2	21		3	NPL	3.02	8	9	2	
95.	1	6	7	10	1		2.8	8	9	2	
96.	1	6	10		3	NPL	3.6	8	9	2	
97.	1	1	3	7	1		3	8	9	2	
98.	1	4	2	5	1		2.5	8	9	2	
99.	1	4	13	18	1		3.8	8	9	2	
100.	1	6	3	6	1		2.57	8	9	2	

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.T.E. Balaji
Postgraduate M.S.(Obstetrics and Gynaecology)
Madras Medical College
Chennai 600 003

Dear Dr.T.E.Balaji,

The Institutional Ethics Committee has considered your request and approved your study titled **"The study on comparison of cervical length measured transvaginally by ultrasonography and Bishop score in predicting successful labour induction" No.20022015.**

The following members of Ethics Committee were present in the meeting held on 03.02.2015 conducted at Madras Medical College, Chennai-3.

1. Prof.C.Rajendran, M.D.,	: Chairperson
2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.R.Nandini, M.D., Inst.of Pharmacology, MMC	: Member
5. Prof.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof.Md.Ali, M.D., D.M., Prof. & HOD of Medl.G.E., MMC	: Member
7. Prof.K.Ramadevi, Director, Inst.of Biochemistry, MMC	: Member
8. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
9. Prof.S.G.Sivachidambaram, M.D.,Director i/c Institute of Internal Medicine, MMC, Ch-3	: Member
10. Thiru S.Rameshkumar	: Lay Person
11. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
12. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

INFORMATION SHEET

- We are conducting a study on "THE STUDY ON COMPARISON OF CERVICAL LENGTH MEASURED TRANSVAGINALLY BY ULTRASONOGRAPHY AND BISHOP SCORE TO PREDICT SUCCESSFUL LABOUR INDUCTION " among patients attending Government Kasturba Gandhi Hospital, Chennai and for that your clinical details may be valuable to us.
- We are selecting certain patients and if you are found eligible, we may be using your clinical details in such a way so as to not affect your final report or management.
- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator Signature of participant

Date: .01.2015

CONSENT FORM

STUDY TITLE : **"THE STUDY ON COMPARISON OF CERVICAL LENGTH MEASURED TRANSVAGINALLY BY ULTRASONOGRAPHY AND BISHOP SCORE TO PREDICT SUCCESSFUL LABOUR INDUCTION"**

STUDY CENTRE : **Institute of Social Obstetrics,**
Government Kasturba Gandhi Hospital,
Chennai-5.

PARTICIPANT NAME : AGE: SEX: I.D.NO:

I confirm that I have understood the purpose of procedure for the above study, I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the possible complications that may occur during the procedure, I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties of published, unless as required under the law. I agree not to restrict the use of any or results that arise from the study.

I hereby consent to participate in this study of "THE STUDY ON COMPARISON OF CERVICAL LENGTH MEASURED TRANSVAGINALLY BY ULTRASONOGRAPHY AND BISHOP SCORE TO PREDICT SUCCESSFUL LABOUR INDUCTION"

Signature of Investigator:

Place : Chennai
Date : .01.2015

Study Investigators Name

Institution

Signature / Thumb Impression of patient

தகவல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

செயற்கை முறையில் முழு கர்ப்பகாலத்தில், பிரசவத்தினை ஏற்படுத்துவதை தீர்மானிக்க, அல்ட்ரா சவுண்ட் முறையில் கர்ப்பவாயின் நீளத்தை அளவிடும் முறையையும், பிஷப் ஸ்கோர் முறையினையும் ஒப்பிட்டு ஆய்வு செய்தல்.

ஆய்வாளர்

மருத்துவர்

சமூக மகப்பேரியல் மற்றும் அரசு கஸ்தூரிப காந்தி தாய் சேய் நல மருத்துவமனை ,

சென்னை மருத்துவ கல்லூரி ,

சென்னை-600005

இந்த ஆய்வில் பங்கு பெறுவது நோயாளிகளின் சொந்த விருப்பத்திலேயே ஆகும். இந்த ஆய்வினால் நோயாளிகளுக்கு எந்த செலவும் இருக்காது, இந்த ஆய்வை ஒட்டி எந்த விதமான சந்தேகங்களுக்கும் விளக்கம் பெற நோயாளிகளுக்கு உரிமை உள்ளது. இந்த ஆய்வின் முடிவுகள் இறுதியில் பிரசுரிக்கப்படும்.

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

செயற்கை முறையில் முழு கர்ப்பகாலத்தில், பிரசவத்தினை ஏற்படுத்துவதை தீர்மானிக்க, அல்ட்ரா சவுண்ட் முறையில் கர்ப்பவாயின் நீளத்தை அளவிடும் முறையையும், பிஷப் ஸ்கோர் முறையினையும் ஒப்பிட்டு ஆய்வு செய்தல்.

ஆராய்ச்சி நிலையம்

சமூக மகப்பேரியல் மற்றும் அரசு கஸ்தூரிப காந்தி தாய் சேய் நல மருத்துவமனை, சென்னை மருத்துவ கல்லூரி , சென்னை-600005

பங்குபெறுபவரின் பெயர்

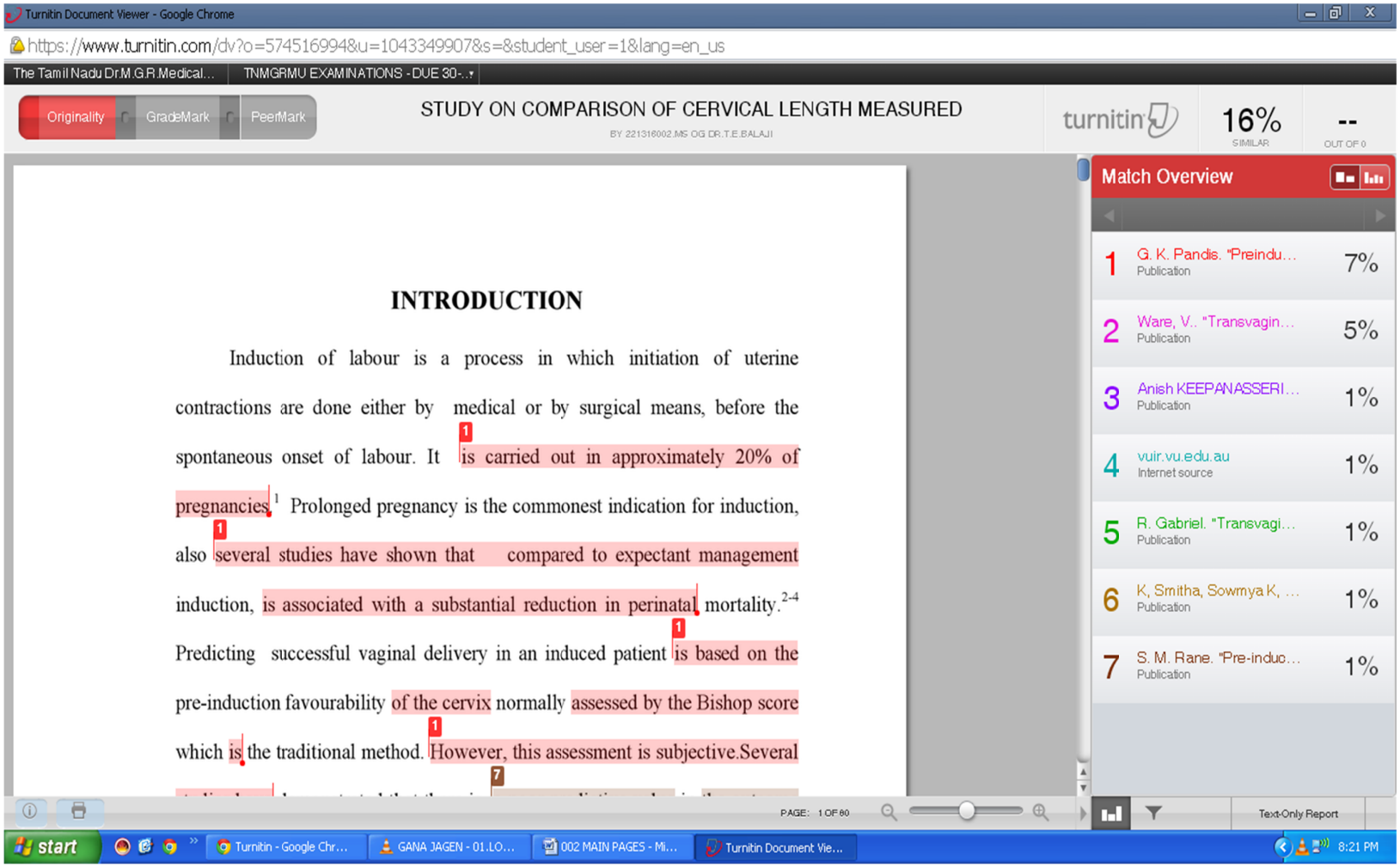
பங்கு பெறுபவரின் எண்

1. மேலே குறிப்பிட்டுள்ளஇந்த மருத்துவ ஆய்வின் விவரங்கள் எனக்கு தெளிவாக விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும் அதற்கான விளக்கங்களை பெறவும் வாய்ப்பு அளிக்கப்பட்டுள்ளது என அறிந்து கொண்டேன்.
2. நான் இந்த ஆய்வில் தன்னிச்சையாக தான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ நான் இந்த ஆய்வில் இருந்து விலக ஆசைப்பட்டால் எந்த பிரச்சனையும் இன்றி விலகலாம் என்றும் அறிந்து கொண்டேன்.
3. இந்த ஆய்வு சம்பந்தமாகவோ , இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் பொழுதோ இந்த ஆய்வில் பங்கு பெரும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவை இல்லை என அறிந்தேன்.
4. இந்த ஆய்வில் பங்கு கொள்ள நான் சுய நினைவோடும் முழு சம்மதத்தோடும் ஒப்புதல் அளிக்கிறேன். எனக்கு கொடுக்கப்பட்டுள்ள அறிவுரைகளின் படி நடந்து கொள்வதுடன் இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதி அளிக்கின்றேன்.

பங்கு பெறுபவரின் பெயர் ஆய்வாளரின் பெயர் :

பங்கு பெறுபவரின் கையொப்பம் ஆய்வாளரின் கையொப்பம்:

தேதி இடம்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INTRODUCTION
Induction of labour is a process in which initiation of uterine contractions are done either by medical or by surgical means, before the spontaneous onset of labour. It is carried out in approximately 20% of pregnancies.[1] Prolonged pregnancy is the commonest indication for induction, also several studies have shown that compared to expectant management induction, is associated with a substantial reduction in perinatal mortality.[2-4] Predicting successful vaginal delivery in an induced patient is based on the pre-induction favourability of the cervix normally assessed by the Bishop score which is the traditional method. However, this assessment is subjective.Several
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INTRODUCTION

Induction of labour is a process in which initiation of uterine contractions are done either by medical or by surgical means, before the spontaneous onset of labour. It is carried out in approximately 20% of pregnancies.[1] Prolonged pregnancy is the commonest indication for induction, also several studies have shown that compared to expectant management induction, is associated with a substantial reduction in perinatal mortality.[2,3] Predicting successful vaginal delivery in an induced patient is based on the pre-induction favourability of the cervix normally assessed by the Bishop score which is the traditional method. However, this assessment is subjective.Several studies have demonstrated that there is a poor predictive value in the outcome of induction especially in women who present with low Bishop score.[4]

Transvaginal ultrasonography has gained increasing significance in the area of induction of labor in obstetrics. Transvaginal cervical length measurement has primarily focused in detecting cervical changes in women those are at risk for preterm delivery.[5] But Theoretically, measurement of the cervix using transvaginal ultrasonography could represent a much more accurate assessment of the cervix than the regular digital examination, because in a closed cervix the supra vaginal portion of the cervix usually comprising about 50% of the cervical length is very difficult to assess digitally. Also in addition, the assessment of the effacement which starts at the internal OS, will be difficult to predict in a cervix that is closed. In contrast transvaginal sonographic measurement of the cervical length is quantitative,it is